EXAMINATION OF THE EFFECT OF CORPORATE INTEGRITY AGREEMENTS ON SKILLED NURSING FACILITY QUALITY OF CARE, AS MEASURED BY RATES OF PRESSURE ULCERS AND INDWELLING CATHETER USE

by
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* The statements and opinions in this dissertation are those of the author only and not of the Federal Government.

ABSTRACT

Problem. Twenty-nine years after passage of the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987), the quality of care in many of our nation's nursing facilities is still a significant problem facing our growing elderly population. Poor quality of care is of concern to nursing facility residents, their families, caregivers, clinical professionals, and to policy makers. In February 2014, the Department of Health and Human Services Office of the Inspector General (HHS-OIG) issued a report which found that an estimated 22 percent of Medicare beneficiaries experienced adverse events during their skilled nursing facility (SNF) stays. With the aging of the United States' population, more individuals, in particular those age 85 and older, will need skilled nursing care in the future; therefore, SNF care quality needs to improve in order to prevent subjecting frail, vulnerable residents to substandard care. Given that Corporate Integrity Agreements (CIAs) are one of the federal government's primary tools to improve quality of care in our nation's poor-performing nursing facilities, it is critical to examine the data to determine if CIAs do, in fact, have a positive effect on skilled nursing quality of care. To date, no study has investigated or validated the significance of CIA impact on skilled nursing facility quality of care.

Methods. This study is a secondary data longitudinal analysis of the effect of quality of care CIAs on SNF care quality, which examined 42 quality of care CIAs covering approximately 1,400 SNFs in the 2003 to 2015 study period. This study had Three Research Objectives: (1) to assess whether quality CIAs had a positive effect on SNF quality of care, as measured by pressure ulcer and indwelling catheter use quality measures (QMs); (2) to assess how certain SNF characteristics and resident case-mix

acuity influenced quality and/or the effect of quality CIAs on SNF quality of care; and (3) to explore the effect of individual CIAs on SNF quality. This study used different analytic approaches to address each of the Three Research Objectives. To test whether quality of care CIAs had an effect on SNF care quality, this study used a mixed effects linear regression model, clustering CIAs and SNFs through use of a random intercept. To assess the influence of SNF characteristics and acuity on quality of care, SNF structural characteristics and SNF resident case-mix acuity were added into the mixed effects linear regression statistical model. The relationships among staffing level, staffing mix, and CIAs were directly examined with regression analysis using staffing levels and staffing mix as outcomes. Finally, to explore the effect of individual CIAs on SNF quality, CIA SNFs that demonstrated improved quality during any CIA phase were identified by performing mixed effects linear regression for each CIA individually. Logistic regression was then used to identify those SNF characteristics that were associated with CIA quality improvement.

Results. This study found that CIAs do not have a significant positive effect on SNF quality, as measured by pressure ulcer and catheter use QMs. Specifically, CIAs did not have a positive effect on pressure ulcer QMs; in fact, pressure ulcer QMs worsened during and after the CIA period. By contrast, CIAs did have a very small positive effect on catheter use QMs during and after the CIA period. In examining the impact of staffing levels and staffing mix on quality, increased staffing levels and staffing mix were associated with improved pressure ulcer QM scores but at a lower magnitude than expected. Conversely, for catheter use QMs, staffing level was negatively associated with catheter use QMs, while staffing mix was positively associated with catheter use

QMs. In examining the association between CIAs and staffing, CIAs were not significantly associated with positive changes in staffing level but were associated with small but statistically significant changes in staffing mix. Examining CIAs one CIA at a time using linear regression served to identify those CIAs whose SNFs improved their pressure ulcer or catheter use QMs during any CIA phase transition. This analysis also identified certain SNF characteristics, i.e., high resident occupancy, higher staffing mix, and high resident case-mix acuity, that were associated with responsiveness of SNFs to CIAs, and are factors that SNFs could adjust to increase their odds of attaining quality improvement under a CIA.

Conclusions. In order to increase the positive effect that CIAs could have on SNF quality, changes to the CIA process should be made in three areas. First, the CIA document itself should be improved by including more prescriptive and concrete requirements for SNFs, such as details about the QM threshold ranges that a SNF should reach by various checkpoints in the CIA and details about how a SNF should staff to acuity. Second, the CIA Quality Monitoring process during the CIA should be improved by requiring the Quality Monitor to engage in more specific and measurable monitoring activities, such as assessing the SNF's leadership quality culture, teaching the SNF staff to track and trend data, and requiring the SNF staff to follow certain evidence-based protocols. And third, and most critically, a post-CIA monitoring process should be developed which would continue to monitor the SNF for two years after its CIA had ended, and which would use the full force of remedies available to the federal government if a SNF failed to improve its care quality. Future research in this area could examine the effect of a CIA on SNF quality by expanding the set of dependent variables

used in this study to include other critical SNF quality measures such as falls, unintended weight loss, antipsychotic use, pain control, nutritional status, and potentially avoidable hospitalizations.

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beach day and sledding day were missed in service to my academic mission and I look forward to full speed ahead in the fun department from now on!

DISSERTATION DEDICATION

I dedicate my dissertation to my husband, Francis L. Swift, Jr., who has been my soulmate and best friend throughout our thirty year journey together, and counting. Every day is beautiful because you, my greatest love, are walking with me hand in hand down life's path experiencing all of life's challenges, triumphs and seasons of change.

I dedicate my dissertation to my dad, John J. Lynch (1922 – 2014), and to my mom, Michaline A. Lynch (1922 – 2015), who provided me with unbounded love, encouragement and support throughout my life, and who taught me the critical importance of carrying justice, fairness, and compassion with me on my journey each day. My parents' experiences aging in place in their golden years have been my inspiration and motivation to devote my career to health and aging policy and law.

Finally, I dedicate my dissertation to all the vulnerable nursing home residents in this nation who deserve quality skilled nursing care. I can only hope that this dissertation is one building block in the effort to improve nursing home care for those, to quote Hubert Humphrey, who are in the twilight of life, the sick, the needy, and the handicapped.

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LIST OF ABBREVIATIONS

ACA	Affordable Care Act
ADLs	Activities of Daily Living
AHRQ	Agency for Healthcare Research and Quality
CASPER	Certification and Survey Provider Enhanced Reporting
CAUTI	Catheter-Associated Urinary Tract Infection
CIA	Corporate Integrity Agreement
CIA Phase 0-1	Transition from Before a CIA to During a CIA
CIA Phase 1-2	Transition from During a CIA to After a CIA
CIA Phase 0-2	Transition from Before a CIA to After a CIA
CMPs	Civil Monetary Penalties
CMS	Center for Medicare and Medicaid Services
CNA	Certified Nursing Assistant
DON	Director of Nursing
EHSI	Extendicare Health Services, Inc.
FCA	False Claims Act
FTE	Full Time Equivalent
GAO	Government Accounting Office
HHS-OIG	Department of Health and Human Services Office of the Inspector General
HIPAA	Health Insurance Portability and Accountability Act of 1996
HPRD	Hours per Resident Day
ICD-9	International Classification of Disease, 9th Edition
IOM	Institute of Medicine

IRB	Institutional Review Board
IRO	Independent Review Organization
LANs	Learning Action Networks
LPN	Licensed Practical Nurse
MDS	Minimum Data Set
NF	Nursing Facility
NHC	Nursing Home Compare
NHC QM	Nursing Home Compare Quality Members
NHRA	Nursing Home Reform Act
NICHE	Nurses Improving Care to Health System Elderly
OBRA 87	Omnibus Budget Reconciliation Act of 1987
OSCAR	Online Survey, Certification, and Reporting System
PHI	Protected Health Information
ProvNumber	Provider Number, how CMS identifies a Skilled Nursing Facility
PU	Pressure Ulcer
QAC	Quality Assurance Committee
QIO	Quality Improvement Organizations
QMs	Quality Measures
RAI	Resident Assessment Instrument
RN	Registered Nurse
SFF	Special Focus Facility
SNF	Skilled Nursing Facility

Chapter I: Introduction – Problem Statement and Three Research Objectives.

> "The United States contends that, from 2007 to 2013, the skilled nursing services provided at Extendicare's SNFs were materially substandard and/or worthless because Extendicare: (a) failed to have a sufficient number and skill-level of nursing staff to adequately care for the SNF residents, (b) failed to provide adequate catheter care to some of the residents, (c) failed to follow appropriate pressure ulcer protocols at the SNFs…."[1]

> "This federal healthcare fraud action arises from defendants' provision of non-existent, grossly deficient, materially substandard and/or worthless nursing home services from 2005 to 2012 at the Oxford Health & Rehabilitation Center in Lumberton, Mississippi ("Oxford"), which caused serious physical and emotional harm to highly vulnerable elderly, disabled, and low-income SNF residents at Oxford."[2]

Twenty-nine years after passage of the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987),[3] the quality of care in many of our nation's nursing facilities that provide skilled nursing care is still a significant problem facing our growing elderly population, and is of concern to nursing facility residents, their families, caregivers, clinical professionals and to policy makers (Mukamel, et al., 2005). This study addresses the question of whether one of the federal government's primary tools to improve the quality of care in SNFs is effective. The federal government (the Department of Justice and the Department of Health and Human Services (HHS)) uses the Corporate Integrity Agreement (CIA) as its primary tool to improve SNF quality. A CIA is an agreement between the federal government and a SNF corporation or single facility SNF which requires the SNF to make system and process changes in order to improve clinical care

[1] Excerpt from the Settlement Agreement between the United States and Extendicare, dated October 3, 2014.
[2] Excerpt from the United States' Complaint in Intervention against Oxford Health and Rehabilitation Center (S.D. Miss), dated February 28, 2013.
[3] OBRA 1987 was passed with the goal of ensuring that skilled nursing facility (SNF) and nursing facility (NF) residents receive quality care. Under OBRA 1987, SNFs and NFs must comply with certain provisions to obtain certification to receive payments from Medicare and Medicaid, such as: regular resident assessments to be used in care planning and surveys to ensure compliance with federal regulations related to staffing and quality of life.

quality and achieve federal regulatory compliance. In a January 29, 2014 speech, Assistant Attorney General Stuart Delery clearly articulated that CIAs are the cornerstone of the federal government's healthcare compliance approach "…as these settlements have made clear, we are not interested in merely collecting a large fine and moving on to the next case. We strive to give companies the incentives – and the tools – to craft better compliance practice in the future."[4]

Specifically, this research study considers whether quality of care CIAs have a positive effect on SNF quality as measured by two quality measures (QMs) – percent of long-stay high-risk residents with pressure ulcers and percent of long-stay residents who have had an indwelling catheter. Given that quality of care CIAs are one of the federal government's primary tools to improve quality of care in our nation's poor-performing SNFs, it is critical to examine the data to determine if quality CIAs do, in fact, have a positive effect on SNF quality of care. To date, no study has investigated or validated the significance of CIA impact on SNF quality of care.

This study focuses on skilled nursing facilities (SNFs)[5] and on nursing facilities (NFs) [6] that provide skilled nursing care and that receive at least some Medicare reimbursement. All SNFs and NFs that provide skilled care are referred to in this study as "SNFs." Nursing facilities that are only reimbursed by Medicaid (just 3% of all

[4] Gaffney, Alexander, "DOJ Says Corporate Integrity Agreements Are Cornerstone of New Compliance Approach," *Healthcare Product Regulation In Focus* (January 29, 2014).
[5] A **SNF** is an institution that provides post-acute **skilled nursing care** or skilled rehabilitation services and is certified by Medicare and/or Medicaid. Skilled nursing and rehabilitative care are services ordered by a physician that require the skills of professional personnel and are provided under the supervision of that personnel such as intravenous injections, administration and replacement of catheters, and administration of prescription medications. (CRS Report 2014).
[6] A **nursing facility** (NF)-only provides **custodial or personal care** (and not skilled care). NF-only care includes assistance with activities of daily living (ADLs), such as bathing, dressing, eating, grooming, ambulating, and toileting. (CRS Report 2014).

nursing facilities) are excluded from this study. As discussed in **Chapter 3, Section 1**, approximately 97% of SNFs and NFs are certified by both Medicare and Medicaid and provide some skilled nursing care.

A. Problem Statement and Significance.

Little could provide more compelling evidence of the significant need to improve SNF care quality than the facts that lie at the center of the *Extendicare*, *Oxford* and *Momence Meadows* cases. In particular, in *Momence Meadows,*[7] the plaintiffs presented evidence of problems at the SNF relating to infection and pest control, pressure ulcer management, medication errors, inappropriate food and water temperatures, and excessive falls. Plaintiffs also offered evidence of incidents where a SNF administrator struck residents, a resident wandered away from the facility, a resident was scalded in a bath, and a resident died from the malfunction of his colostomy bag. At trial in the United States District Court for the Central District of Illinois, the jury awarded the Relator-plaintiffs[8] and the United States over $3 million in compensatory damages and imposed about $19 million in fines for the Relator-plaintiffs' claims.

Individual cases of poor SNF care quality are merely examples of a much larger national trend of poor quality SNF care as determined by the Department of Health and Human Services Office of the Inspector General (HHS-OIG). In February 2014, the HHS-OIG issued a report which found that an estimated 22 percent of Medicare

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[7] *U.S. ex rel. Absher v. Momence Meadows Nursing Center*, et al., 13-1396 (7th Cir. 2014). Further, recent HHS-OIG investigations have found a number of SNFs that have failed to provide adequate care to their residents. In one case, five SNFs did not provide adequate staffing and services to beneficiaries, resulting in beneficiaries developing pressure ulcers, malnutrition, dehydration, and side effects from not receiving medications. (HHS-OIG Report 2012). In another case, three SNFs were charged with providing inadequate food and medication to their residents. *Id*. In a third case, inadequate staffing caused numerous residents to develop pressure ulcers, some of which were left untreated. *Id*.

[8] A Relator in a federal healthcare fraud case is the whistleblower who brings the case to the government's attention.

beneficiaries experienced adverse events[9] during their SNF stays (HHS-OIG 2014 Report). These adverse events included medication-induced delirium, exacerbation of pre-existing conditions resulting from an omission of care, and surgical site infection associated with wound care. An additional 11 percent of Medicare beneficiaries experienced temporary harm events during their SNF stays, such as pressure ulcers and falls or other trauma with injury associated with poor resident care. *Id.* **Table 1-1** below shows adverse events identified among Medicare SNF residents by category of harm.

Table 1-1 - Adverse Events Identified Among Medicare SNF Residents by Category[10]

Types of Adverse Events		Percentage
Events Related to Medication		37%
	• Medication-induced delirium or other change in mental status	12%
	• Excessive bleeding due to medication	5%
	• Fall or other trauma with injury secondary to effects of medication	4%
	• Constipation, obstipation, and ileus related to medication	4%
	• Other medication events	14%
Events Related to Resident Care		37%
	• Fall or other trauma with injury related to resident care	6%
	• Exacerbations of preexisting conditions resulting from an omission of care	6%
	• Acute kidney injury or insufficiency secondary to fluid maintenance	5%
	• Fluid and other electrolyte disorders (e.g., inadequate management of fluid)	4%
	• Venous thromboembolism, deep vein thrombosis (DVT), or pulmonary embolism (PE) related to resident monitoring	4%
	• Other resident care events	14%
Events Related to Infections		26%
	• Aspiration pneumonia and other respiratory infections	10%
	• Surgical site infection (SSI) associated with wound care	5%
	• Urinary tract infection associated with catheter (CAUTI)	3%
	• *Clostridium difficile* infection	3%

[9] The HHS-OIG Report defines 'adverse events' as harm to a resident that is the result of medical care, including failure to provide needed care. Adverse events include medical errors but they also include more general substandard care that results in resident harm, occurring in the areas of medication administration, resident care, and infections. (HHS-OIG 2014 Report).
[10] HHS-OIG 2014 Report.

Types of Adverse Events		Percentage
	• Other infection events	5%

In fact, HHS-OIG found that 59 percent of these adverse events and temporary harm events were clearly or likely preventable. *Id*. The HHS-OIG attributed this preventable harm to substandard care, inadequate resident monitoring, and failure or delay of necessary care. **Table 1-2** below shows adverse and temporary harm events by preventability determination.

Table 1-2 - Adverse and Temporary Harm Events by Preventability Determination[11]

	Percentage of Adverse Events	Percentage of Temporary Harm Events	Percentage of All Events
Preventable—Harm could have been avoided through improved assessment or alternative actions	69%	46%	59%
Clearly preventable	18%	6%	13%
Likely preventable	50%	40%	46%
Not preventable—Harm could not have been avoided given the complexity of the resident's condition or care required	29%	47%	37%
Clearly not preventable	11%	12%	11%
Likely not preventable	18%	35%	26%
Unable To Determine Preventability[12]	3%		4.2%

The 2014 HHS-OIG Report found that over half of the residents who experienced harm returned to a hospital for treatment, which cost Medicare approximately $208 million during the HHS-OIG study period of 2008 to 2012. Of this $208 million spent on hospitalizations, the HHS-OIG found that $136 million was spent on hospitalizations associated with preventable events. *Id*. **Table 1-3** below shows the costs of hospitalizations associated with these adverse events.

[11] HHS-OIG 2014 Report.
[12] HHS-OIG 2014 Report. This term means - unable to reliably project the weighted point estimate for temporary harm events classified as "Unable to Determine" because of the small number of sample occurrences.

Table 1-3 - Costs of Hospitalizations Associated With Adverse Events[13]

Hospitalization Type	Estimated Number of Hospitalizations	Estimated Average Costs	Estimated Total Spending
Hospitalizations for medication events	7,203	$8,372	$57,729,935
Hospitalizations for resident care events	7,511	$8,967	$67,350,098
Hospitalizations for infections events	5,679	$14,599	$82,899,180
Hospitalizations Associated With All Events	20,393	$10,276	$207,979,213

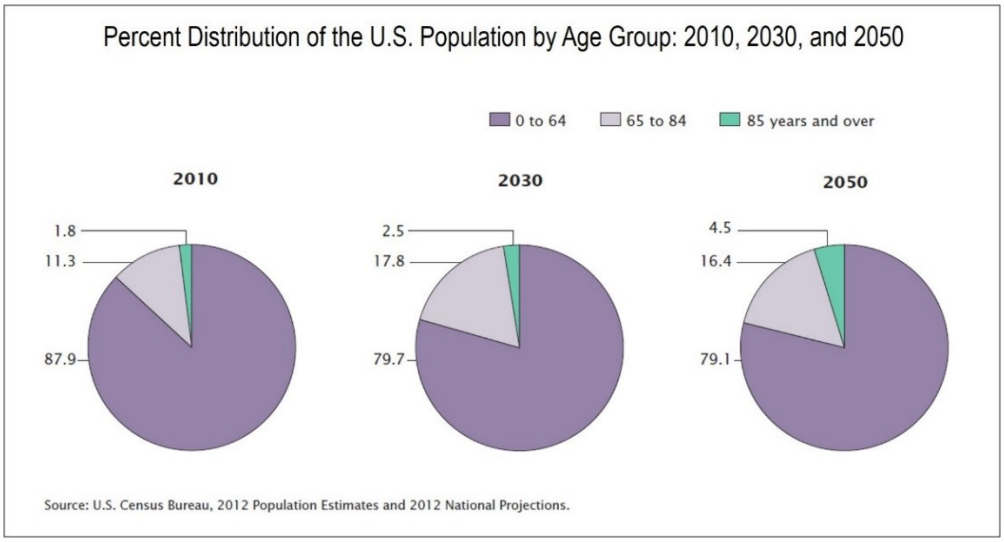
The scientific literature further supports that there are widespread quality problems in many SNFs, including inadequate assistance with eating, false charting, inadequate toileting assistance and turning of residents, residents left in bed most of the day, little walking assistance, untreated pain, and untreated depression (Harrington, 2005, Castle, et al., 2007).

These quality problems in many of our nation's SNFs are significant because poor quality of care in these facilities harms vulnerable elderly or disabled residents and increases Medicare costs in particular, in the form of avoidable hospitalizations. Currently, in the United States, approximately 1.6 million elderly and disabled individuals rely on the care of one of this nation's approximately 16,000 SNFs and NFs (Castle et al., 2010). With the aging population of the United States, more individuals will need skilled nursing care in the future, in particular those aged 85 and older. *Id.* It is estimated that these individuals will need skilled nursing care for between three and five years on average (Kaiser Report, June 2013). By 2050, the number of people age 85 and older is expected to grow to 19 million and many of these people will need long-term care. *Id*. As shown in **Figure 1-1** below, a U.S. Census Bureau Report shows that while

[13] HHS-OIG 2014 Report.

1.8% of the U.S. population was 85 years old and older in 2010, 4.5% of the U.S. population will be 85 and older in 2050. (Colby, et al., 2014).

Figure 1-1 – Percent Distribution of U.S. Population by Age Group



In the past decade, Medicare expenditures for SNF care have more than doubled. (HHS-OIG 2014 report). In 2000, Medicare paid $12 billion for SNF care and, in 2010, Medicare paid $26 billion for SNF care (again, SNF care is defined as skilled care in a skilled nursing facility or in a nursing facility). Medicare accounts for approximately 14% of nursing facility payments; Medicaid is the primary payer for nursing facilities accounting for approximately 63% of care payments; and private pay accounts for about 22% of nursing facility payments (Kaiser Report, June 2013).

B. Background on Federal Healthcare Fraud Cases and Resulting Corporate Integrity Agreements.

1. Federal Healthcare Fraud Cases.

SNFs that violate federal healthcare fraud laws are usually required to enter into a quality of care CIA with the federal government in order to avoid exclusion from federal healthcare programs. One way in which SNFs violate federal healthcare fraud laws is

when they 'knowingly' bill Medicare and Medicaid for ***worthless skilled nursing services*** – services that fail to provide adequate skilled nursing care for their residents. The False Claims Act (FCA), 31 U.S.C. 3729 *et seq.*, is "the primary Government vehicle for recouping losses suffered through fraud." H.R. Rep. No. 99-660 at 18 (1986). The FCA prohibits any person from knowingly submitting "a false or fraudulent claim for payment or approval," 31 U.S.C. 3729(a)(1) (2008). The FCA's knowledge requirement encompasses not only actual knowledge of falsity, but also deliberate ignorance and reckless disregard of the truth. *See* 31 U.S.C. 3729(b)(1). The FCA imposes civil penalties and treble damages as remedies for each healthcare fraud violation. *See* 31 U.S.C. 3729(a).

A number of federal circuit and federal district court cases have found that SNFs that knowingly make claims for payment for worthless skilled nursing services have liability under the FCA.[14] 'Worthless services' under the FCA address instances where *either* skilled nursing services literally were not provided *or where the skilled nursing service was so substandard as to be tantamount to no service at all*. In *United States v. Houser*, Crim. Case 4:10-cr-00012-HLM-WEJ (N.D. Ga. April 2, 2012), the court applied the worthless services theory to find the defendant SNF operator guilty of criminal healthcare fraud:

> A worthless services claim stands for the unexceptional proposition that an entity may not bill the Government for products or services that are not rendered, or that are so deficient that they have no value to the resident, or are totally undesirable. Worthless services are services that are so inadequate, deficient, and *substandard*, or so completely lacking in value or of no utility to the resident, that a

[14] *See, e.g., United States ex rel. Mikes v. Strauss*, 274 F.3d 687, 703 (2d Cir. 2001); *United States v. Cathedral Rock Corp*., No. 03-1090, 2007 WL 4270784, at *6 (E.D. Mo. Nov. 30, 2007); and *United States v. Villaspring Healthcare Center*, 2011 WL 6337455, at *4 (E.D. Ky. Dec. 19, 2011).

> reasonable person would understand that any services provided were worthless.

Houser, (emphasis added).

Federal healthcare fraud cases consistently uncover staffing as a root cause of substandard care in SNFs. Many nursing homes providing skilled care operate with what experts have concluded to be suboptimal staffing characteristics: low RN, LPN, and CNA staffing levels, high staff turnover rates, high use of agency staff (temporary workers), and a low professional staff mix (meaning a low ratio of RNs to LPNs and CNAs). (Castle, et al., 2011). Federal healthcare fraud cases reveal that staffing can be controlled by SNF corporate management as a way to maintain corporate profits instead of as a way to ensure that staffing levels are adequate to address the residents' needs and to prevent resident harm. For example, in the Skilled Healthcare Group (Skilled) SNF healthcare fraud trial in California in 2011, the following e-mail evidence was introduced at trial which underscores the problem with corporate management maintaining unacceptably low staffing levels in SNFs in an effort to achieve a desired profit margin:[15]

An e-mail from sent from a Skilled VP to facility administrators on November 22, 2005:

> "Guys – we need to absolutely tighten up the hours ppd, overtime reduction, the wages ppd and the amount of % increases we are giving. Please obviously work to pump up total census days and make sure you direct your administrators to staff for a census that is 2% lower than they actually are running."

> An e-mail from a facility administrator to a VP dated July 25, 2007:

> "4 of 5 buildings were under 3.2 for the week. We need staffing. We just received notification this morning of yet another 3.2 deficiency from DHS for Granada. I'm all about census but we need staff to get census."

[15] *Lavender v. Skilled Healthcare Group* (May 2006).

These e-mails underscore that some SNFs are being run with too few clinical staff in order to drive down labor costs and to increase profits at the expense of resident care.

The Medicare program reimburses SNFs to provide skilled nursing services and skilled rehabilitation therapy. Further, sections (b), (c), and (d) of the Nursing Home Reform Act (NHRA) and their regulations contain essential quality of care provisions that lie at the heart of the bargain between the federal government and SNFs. *See* 42 U.S.C. § 1395i-3(b), (c), and (d); 42 C.F.R. §§ 483.13 - 483.70. For example, Section 483.25 of the NHRA mandates that "each resident must receive and the SNF must provide the necessary care and services to ***attain or maintain the highest practicable physical, mental, and psychosocial well-being***, in accordance with the comprehensive assessment and [resident's] plan of care." (emphasis added). This section further requires that SNFs provide basic treatment to prevent pressure ulcers (§ 483.25 (c) (2)); to prevent falls and other accidents (§ 483.25 (h) (2)); to maintain proper nutrition and hydration (§ 483.25 (j)); and to prevent medication errors and over-medication of residents (§ 483.25 (l) (1) and (m) (2)). Congress underscored the materiality of these essential skilled nursing services by authorizing the Secretary of Health and Human Services to "deny any further payments" to SNFs that fail to provide these skilled nursing services. If these services are not provided, or provided so poorly as to be worthless, the SNF provider is not entitled to payment.

CMS regulations and guidelines make clear that SNFs must remain in continual compliance with the applicable provisions of the NHRA, 42 C.F.R. §§ 483.1 *et seq.* The *CMS State Operations Manual Chapter 7 - Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities* states:

> The regulation emphasizes the need for continued, rather than cyclical compliance. The enforcement process mandates that policies and procedures be established to remedy deficient practices and to ensure that correction is lasting; ***specifically, that (SNF and NF) facilities take the initiative and responsibility for continuously monitoring their own performance to sustain compliance***.[16] (emphasis added).

Similar to the federal government, many states also have False Claims Act statutes which allow the states to prosecute nursing facilities providing skilled care in order to recover state Medicaid payments. Specifically, thirty states have state False Claims Act provisions.[17]

2. Resulting Corporate Integrity Agreements.

If a SNF is subject to an FCA federal civil prosecution and settles an FCA worthless services case with the federal government through the United States Department of Justice, that SNF is usually required to enter into a quality of care CIA with HHS-OIG in order to avoid exclusion from federal healthcare programs.[18]

a. Description of a Quality of Care CIA and its Purpose.

A quality of care CIA is an enforcement tool used by HHS-OIG to improve SNF quality of care and to promote compliance with healthcare regulations. Quality of care CIAs are typically 5 years in duration.[19]

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[16] *Id., § 7000,* http://www.cms.gov/manuals/downloads/som107c07.pdf (emphasis added).
[17] Taxpayers Against Fraud Education website, located at http://www.tax.org, accessed on January 3, 2016. The 30 states with state false claims act provisions are: California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, and Washington.
[18] Pursuant to 42 U.S.C. Section 1320a-7, HHS-OIG may exclude entities from participation in Medicare, Medicaid, and other Federal healthcare programs.
[19] If, while a SNF corporation is under a CIA, the entity sells facilities, splits into multiple corporations or reorganizes to form a new corporation, those individual SNFs that are sold or those that are under the newly-formed corporation are placed under 'successor CIA agreements' to ensure that these SNFs fulfill the quality improvement requirements of the original CIA. (2009 HHS-OIG).

The purpose of a quality CIA is to focus on the SNF's systemic care issues, not individual facility problems, and to focus on the SNF's internal system of quality assurance and improvement.[20] As discussed in detail in **Chapter 2**, a SNF placed under a CIA is generally required to: hire a compliance officer or Quality Monitor and appoint a compliance committee; develop written standards and policies; implement a comprehensive employee training program; retain an Independent Review Organization (IRO) to review claims submitted to Federal healthcare programs; establish a confidential disclosure program; restrict employment of ineligible persons; report overpayments, reportable events, and ongoing investigations; and provide an implementation report and annual report to the HHS-OIG on the status of the entity's compliance activities.[21] **See Appendix A, Quality of Care CIA Table** (describes any unique provisions of all 42 of the quality of care CIAs that are part of this study).

If a SNF corporation or single facility SNF fails to comply with its CIA, HHS-OIG may impose civil monetary penalties (CMPs), or if the SNF materially breaches the CIA, HHS-OIG may exclude one or more of the SNF's individual facilities from participation in Federal healthcare programs (2009 HHS-OIG study).

b. How a SNF Can Become Subject to a CIA.

A SNF entity can become subject to a quality CIA in two ways: (1) by being the target of a federal civil healthcare fraud prosecution by the Department of Justice, or (2)

[20] Quality of care CIAs are not the only type of CIA that HHS-OIG enters into with a provider. HHS-OIG also requires a basic CIA in federal healthcare fraud settlements with many other types of providers for many other types of fraud (that are not quality of care healthcare fraud), such as: billing fraud, DME fraud, and mispricing of drugs. Quality of care CIAs differ from other HHS-OIG CIAs in that quality of care CIAs require an Independent Quality Monitor, Quality Assurance Monitoring Committees, internal audit requirements, and extensive policies, procedures and training related to quality of care.

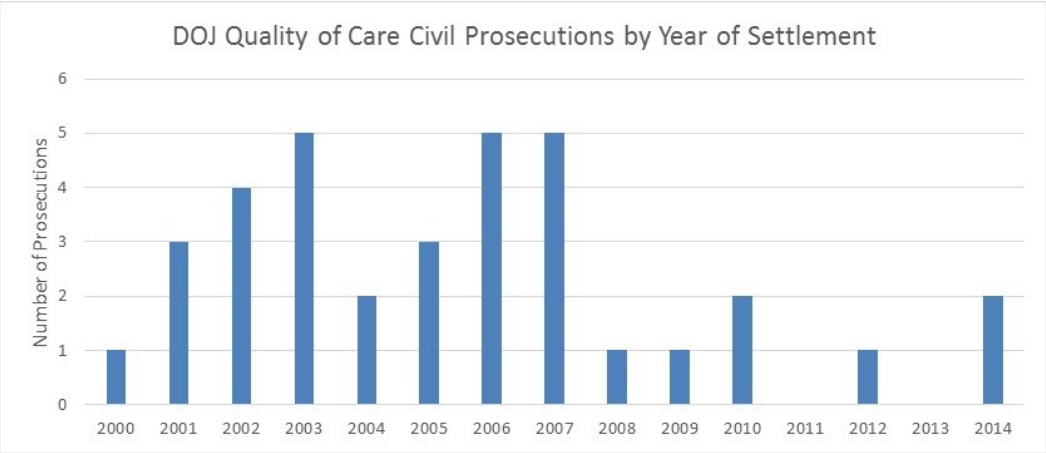
[21] *See*, the Department of Health and Human Services, Office of the Inspector General Quality of Care CIA discussion located at http://oig.hhs.gov/compliance/corporate-integrity-agreements/quality-of-care.asp, accessed on November 24, 2015.

by being identified by HHS-OIG as a provider whose quality of care is so deficient that a CIA is needed to improve severely substandard SNF resident care. The overwhelming majority of SNFs become subject to a CIA as a result of a Department of Justice healthcare fraud prosecution.

There are essentially three ways in which a SNF corporation or single facility SNF could become a target of a healthcare fraud prosecution by the Department of Justice. First, the Department of Justice routinely examines the Nursing Home Compare Quality Measure (QM) scores for many large national and regional SNF corporations. Those SNF corporations that flag with problematic QMs can become the target of a healthcare fraud investigation. Second, CMS monitors the SNFs' QMs, deficiency rates, and overall state survey results for individual SNFs. Those individual SNFs that have problematic QMs, deficiency rates, and overall state survey findings are often referred by CMS to the Department of Justice for investigation. The third way in which a SNF could become subject to a federal healthcare fraud prosecution, and thereby to a quality CIA, is by being a defendant in a whistleblower lawsuit which is often filed by an ex-employee of a SNF and alleges quality of care problems at a single facility SNF or corporation-wide at all the SNF's facilities.

Over the time period of this longitudinal study from 2003 to 2015, there has not been any significant trend in DOJ civil healthcare fraud prosecutions. As shown below in **Figure 1-2**, DOJ civil fraud prosecutions of worthless services cases have ebbed and flowed over the study period with particular spikes in volume of prosecutions in 2003, 2006, and 2007.

Figure 1-2 – DOJ Quality of Care Civil Prosecutions



c. An Overview of the Nation's Quality of Care CIAs.

The nation's first SNF quality of care CIA went into effect in June 2000. From June 2000 to present, there have been approximately 42 CIAs with both large corporate SNF chains and single facility SNFs. **See Appendix A, Quality of Care CIA Table**. Of note, in November 2014, the SNF corporate chain Extendicare signed a groundbreaking quality of care CIA with HHS-OIG. This CIA was significant because it covered Extendicare's entire corporate chain of 146 SNF facilities and it required Extendicare to develop a unique Staffing Review Committee in order to ensure that Extendicare would staff its SNFs to acuity (Extendicare CIA 2014). See **Appendix B, Extendicare CIA.** Staffing to acuity requires Extendicare to regularly review the care needs of its residents and to staff its SNFs with the appropriate number and skill level of RNs, LPNs, and CNAs to support its SNF residents' care complexity.

*C. **Three Research Objectives**.*

My research study had three objectives. My primary research objective was to examine whether quality of care CIAs had a positive effect on SNF quality of care, as measured by two NHC quality measures (QMs) – percent of long-stay high-risk residents

with pressure ulcers, and percent of long-stay residents who have had an indwelling catheter (both as defined in MDS 2.0 and MDS 3.0.) This primary objective examined whether quality CIAs had a positive effect on SNF care quality over and above any unrelated national SNF quality of care trends. An ancillary research objective was to determine when any CIA effect on these two QMs occurred or persisted – that is, did any CIA effect occur before the SNFs officially entered into CIAs, during the CIA period, and/or after the SNFs completed the CIAs.

My second research objective was to assess how, if at all, certain SNF structural characteristics and SNF resident case-mix acuity influenced the effect of a CIA on SNF quality of care and influenced SNF care quality. An ancillary research objective here was to examine the effect of CIAs on staffing directly by setting staffing level and staffing mix as output variables and determining if CIAs were associated with changes in staffing.

My third research objective was to explore the effect of individual CIAs on SNF quality, and to examine the specific characteristics of those SNFs that showed quality improvement under their CIAs.

Chapter II: Literature Review.

This Literature Review Chapter analyzes the scientific literature, government reports, and federal healthcare documents addressing issues relevant to the effect of CIAs on SNF quality of care, as defined by two quality outcome measures – rates of pressure ulcers and of indwelling catheter use. Specifically, this Chapter is divided into thirteen sub-sections: (1) Literature Review methodology, including a literature search for any previous CIA studies; (2) CIA structure and content, evolution, and SNF corporations' stated challenges with CIAs; (3) discussion of one previous primarily qualitative study of the effectiveness of quality CIAs and of a CMS SNF quality improvement program; (4) history of the federal regulation of the SNF industry and recent proposed amendments to SNF regulations; (5) the CMS SNF Survey and Data Collection Systems; (6) the changing nature of the SNF industry and SNF residents over the study period; (7) regional variation in SNF quality; (8) accepted measures of SNF quality; (9) evidence-based protocols for pressure ulcer prevention and for reducing indwelling catheter use; (10) CMS guidance and quality improvement initiatives during the study period related to pressure ulcer prevention and reducing indwelling catheter use; (11) the effect of certain SNF structural characteristics on SNF quality of care: for-profit status, payer-type, occupancy rate, and acuity; (12) the effect of staffing on SNF quality of care, including recent proposals related to a federal mandatory minimum nurse staffing minimum level; and (13) a discussion of the gaps in the scientific literature that support the need for this CIA study. This Literature Review informed my study design, selection of covariates and potential confounders, and my statistical analyses.

A. Literature Review Methodology.

My literature review methodology followed a four-step process: (1) literature searches; (2) inclusion criteria review; (3) article abstraction and analysis; and (4) a final step which was to specifically search for any previous CIA effectiveness studies (Nakrem, et al., 2008). First, a systematic electronic search for relevant scientific articles, government reports, and federal healthcare documents was performed in the following databases: MEDLINE, PUBMED, CINAHL, PsycINFO, *Cochrane Collaboration,* and the TRIP databases. The search terms used were: "skilled nursing facility," "nursing home," "quality," "quality improvement," "performance improvement," "quality indicator," "quality measure," "measure nursing home quality," "pressure ulcer," "catheter," "MDS 2.0 and/or MDS 3.0," "nursing home staffing," "nursing home ownership," "nursing home and/or facility factor," "staffing and quality," "nursing home and/or facility characteristics," "nursing home and profit or not-for-profit or non-profit and quality," and "MDS and reliability." The search timeframe was limited to January 1, 1998 to September 30, 2015, inclusive. These search terms were also run in GOOGLE Scholar and relevant government websites (such as the Centers for Medicare and Medicaid Services, the Department of Health and Human Services Office of the Inspector General, and the Federal Bureau of Investigation), where the first 10 hits were reviewed and analyzed. Additionally, hand searches in references lists from relevant scientific articles and reports found in the above-described searches were performed. Finally, personal communication with experts in the gerontology field, in federal aging policy, and in relevant non-profit organizations supplemented my literature searches.

The second step in the literature review process was to review and analyze scientific articles and reports for inclusion. Articles were included for analysis if they addressed the following topics: effectiveness of quality improvement programs in SNFs; the business of the SNF industry; regional variation in SNF quality; accepted measures of SNF quality; clinical pathways to improving rates of pressure ulcers and indwelling catheter use; CMS programming related to pressure ulcer and catheter use in SNFs; the effect of SNF structural characteristics on care quality; the effect of SNF resident case-mix acuity on care quality; the effect of staffing on SNF quality; and mandatory minimum SNF nurse staffing levels. Finally, all articles meeting the inclusion criteria were abstracted for relevance, quality of evidence, and for final inclusion in this Literature Review Chapter.

After I completed the first three steps in my general literature review, I engaged in a final review step to ensure that I had located any studies addressing CIAs or CIA effectiveness. I searched for the terms "Corporate Integrity Agreement" or "CIA" or "HHS and Quality Improvement" in the scientific databases described above, in Google Scholar, and on the following government websites: HHS-OIG, DOJ, CMS, and GAO. Finally, I interviewed experts in the skilled nursing facility quality field, including HHS-OIG attorneys, current and former CIA Quality Monitors, and CMS Division of Nursing Home Directors. My research revealed that only one (primarily qualitative) study had addressed CIA effectiveness and there were no studies in the literature which investigated or validated the significance of CIA impact on SNF quality of care, investigated or validated the influence of SNF structural factors, staffing levels, and SNF resident case-mix acuity on CIA impact, and there were no studies which determined the significance

of any differences between national SNF QM averages and CIA-covered SNF QM averages. Therefore, as discussed in this Chapter in **Section M**, these gaps in the scientific literature support the need for this CIA study.

B. CIA Basic Structure and Content, Evolution of the CIA Document over the Study Period, and SNF Corporations' Stated Challenges with CIAs.

1. CIA Structure and Content.

All HHS-OIG quality of care CIAs have essentially the same standard structure and, in large part, the same fundamental requirements for SNFs.[22] However, some individual CIAs do have important, unique provisions that are tailored to the individual federal healthcare case on which the CIA is based. **Appendix A** contains a detailed analysis of the 42 CIAs that are the subject of this study and highlights key provisions of certain CIAs that are unique and worthy of note. **Appendix B** contains a sample quality CIA document (the Extendicare Health Services, Inc. (Extendicare) CIA with an effective date of October 3, 2014).

Generally, quality of care CIAs have the structure and content documented in this Section. In the *Preamble* to the CIA, the specific SNF corporate entities are defined and it is noted whether the SNF corporation or SNF entity had any type of voluntary compliance program before the start of the CIA. The *Terms and Conditions* section of the CIA addresses the term of the CIA which is usually five years. The *Terms* section also addresses the scope of the CIA, meaning the 'covered persons' (based on 5% SNF ownership) and the 'relevant covered persons' (based on clinical resident caregiving

[22] *See*, the Department of Health and Human Services, Office of the Inspector General Quality of Care CIAs, located at http://oig.hhs.gov/compliance/corporate-integrity-agreements/quality-of-care.asp, accessed on November 24, 2015.

responsibilities). Covered individuals typically include SNF officers, directors, employees, contractors, and agents.

The *Corporate Integrity Obligations* section of the CIA requires the SNF corporation or SNF entity to: (1) establish and maintain a compliance program that has a compliance officer and to appoint a corporate-level Quality Assurance Committee (QAC) to oversee clinical improvement and compliance issues throughout the SNF corporation;[23] the QAC is required to meet monthly, to create a quality of care review program that will perform internal quality audits and reviews, and to create a quality of care dashboard to function as a quality of care scorecard for the entity; (2) create a special committee of its Board of Directors, which would meet at least quarterly, to review quality outcomes and the entity's compliance with the CIA; (3) some CIAs require the SNFs to create a staffing review committee to assess the nurse staffing provided at the facility, to make recommendations regarding staffing, and to assess on an ongoing basis whether the entity is providing the quality, quantity and composition of nursing staff necessary to meet the residents' needs at the SNF; and (4) to develop a written Code of Conduct for the SNF corporation and entities regarding adherence to federal healthcare standards, and compliance with the CIA requirements (including meeting appropriate care quality and staffing levels appropriate to meet the residents' needs).

Under the *Corporate Integrity Obligations* section of the quality CIA, the entity is also required to: (1) provide competency-based training and education to 'covered

[23] Pursuant to 42 C.F.R. Section 483.75(o)(2)(i), each SNF is required to have a Quality Assurance and Assessment Committee. The Committee must meet at least once a quarter and membership must include the Director of Nursing, a physician, and at least three other members of the SNF staff.

persons' and 'relevant covered persons' related to CIA requirements and compliance program requirements; the entity is also required to provide training to the Board of Directors related to the responsibilities of the Board under the CIA and corporate governance; (2) retain an Independent Review Organization (IRO) approved by HHS-OIG with the responsibility to audit the entity's Minimum Data Set (MDS) coding, among other issues; the IRO audits typically include an operational review of the organization's process for compiling and submitting claims; (3) retain an Independent Quality Monitor (Quality Monitor) at the entity's expense who will assess the entity's quality control systems, response to quality of care issues, proactive steps to ensure that each resident receives quality care, self-review of quality matrices, and maintenance of the entity's dashboard; (4) ensure that the Quality Monitor has unfettered access to the SNF's facilities, staff, residents, documents, and management at all levels of the SNF organization; (5) establish a confidential disclosure program to permit an individual to report issues with the entity's policies or practices related to quality of care or a federal healthcare program believed by the reporter to be a potential violation of criminal, civil, or administrative law; and (6) establish a screening program to ensure that ineligible persons are not hired; and (7) submit status reports to HHS-OIG and report certain events such as serious quality of care problems to the IRO and to HHS-OIG within required timeframes.

Each quality CIA also contains a standardized, detailed *Policies and Procedures* section which identifies those clinical care and billing areas where the Quality Monitor will focus attention. Pursuant to this Section, a SNF is specifically required to: (1) ensure that the SNF complies with all applicable requirements of Medicare's Prospective

Payment System (PPS); (2) ensure the accuracy of its Minimum Data Set (MDS) as specified by the Resident Assessment Instrument (RAI) User's Manual; ensure that its facilities are appropriately and accurately using the current Resource Utilization Group (RUG) classification system; (3) ensure the accuracy of its billing and cost report preparation policies and procedures; (4) ensure the provision of coordinated interdisciplinary care to its long-term care residents, including, but not limited to the following areas addressed in 42 CFR Part 483: resident assessment and care planning; nutrition; disease-specific care; wound care; infection control; appropriate drug therapies; appropriate mental health services; provision of basic care needs, including the provision of Activities of Daily Living (ADLs); incontinence care; resident rights; avoiding physical and chemical restraint use; therapy services; quality of life, including accommodation of needs and activities; assessment of resident competence to make treatment decisions; and professional services; (5) ensure that staffing is in compliance with the Federal healthcare program requirements and state laws, and is not based on financial requirements; (6) minimize the number of individuals working at the SNF who are on temporary assignment or not employed by the SNF; (7) effectively collect and analyze staffing data, including staff-to-resident ratios and rate of staff turnover; and to (8) ensure that all SNF residents are served in the least restrictive environment and most integrated setting appropriate to their needs.

Under the *Successor Liability* section of the quality CIA, the entity is required to: (1) notify HHS-OIG of the closure of any SNF subject to a CIA; (2) notify HHS-OIG of the purchase of a SNF that is subject to a CIA; and (3) notify HHS-OIG of the sale or

transfer of a SNF that is subject to a CIA. In the case of the sale of a SNF subject to a CIA, that CIA "shall be binding on the purchaser or transferee of the SNF."[24]

Under the *Implementation and Annual Reports* section of the quality CIA, the entity is required to: (1) prepare a report to HHS-OIG, within six months of entry into the CIA, summarizing the entity's status of implementation of the requirements of the CIA and (2) prepare an annual report of the corporation SNFs' or the single SNF's compliance during the reporting period on such issues as composition of the Board and QAC, outcome measure assessments, tracking of performance matrices, and a summary of reportable events. The annual report also typically includes the results of the IRO's review of the organization's compliance with the terms of the CIA.

Finally, under the *Breach and Default* section of the quality CIA, the entity is subject to the following penalties if the SNF corporation or individual SNF fail to fully comply with all of its CIA obligations: (1) the SNF corporation or individual SNF can be compelled to provide specific performance by an Administrative Law Judge on HHS-OIG's motion; (2) the SNF corporation or individual SNF can be subject to stipulated penalties ranging from $2,500 a day to $50,000 per offense for offenses ranging from failing to pay its Monitor to filing a false certification on its required annual report, respectively; and (3) exclusion from participation in federal healthcare programs for a 'material breach' of its CIA, which includes conduct such as failure to report a reportable event, a violation of an obligation that has an impact on resident care, or failure to utilize the IRO and Monitor as required by the CIA.

[24] *See*, the Department of Health and Human Services, Office of the Inspector General Quality of Care CIA, located at http://oig.hhs.gov/compliance/corporate-integrity-agreements/quality-of-care.asp, accessed on November 24, 2015.

2. Evolution of the CIA Document over the 2003 to 2015 Study Period.

In assessing the effectiveness of CIAs over the 2003 to 2015 study period, it is important to consider that the standard CIA document has evolved somewhat systematically since implementation of the first CIA (all of the unique provisions, if any, of each of the 42 CIAs that are the subject of this study are identified in the CIA Table in **Appendix A**). The first CIA in my study is the Beverly Enterprises, Inc. ("Beverly") CIA, signed in 2000. This CIA contained a bare minimum of provisions designed to ensure that Beverly complied with 42 CFR Section 483, captured and reported billings accurately, did not retaliate against anyone for reporting non-compliance, and administered disciplinary action for policy violations. This 'progenitor CIA' with its "bare bones" requirements established a baseline for all subsequent CIAs.

The second "generation" of CIAs, from the 2001-2004 timeframe and including, for example, the 2001 CIA with Vencor and the 2002 Beverly Amendments, built on the original Beverly CIA and introduced a number of new provisions, including requirements for residents to receive coordinated, interdisciplinary care in the least restrictive, most integrated environment possible, and required staffing according to federal law and to meet residents' needs. In addition, CIA agreements from this time period required accurate reporting (including staffing information) consistent with the Resource Utilization Group (RUGs) and Minimum Data Set (MDS) reporting systems.

The third generation of CIAs, from the 2005–2010 timeframe included, for example, the 2005 Integrated Health Services, Inc. (IHS) CIA and the 2006 Pleasant Care CIA (and its successors). The CIAs from this time period also built on the previous CIAs, but additionally expanded several quality compliance areas and reorganized many of the key CIA policy requirements. For example, the 2005 IHS CIA contained a bulleted

list of eleven separate elements which fully described the coordinated interdisciplinary care required of SNFs, specifically addressing nutrition, ADLs, use of restraints, and wound care. CIAs in this time period also focused on the treatment of certain clinical conditions. For example, the 2006 Pleasant Care CIA (and its successors) included language addressing falls and falls protocols; and the 2007 Green Acres CIA included policy requirements for the care and treatment of pressure ulcers and diabetes.

Finally, the current "generation" of CIAs, from 2011 to the present, have removed some of the "boiler plate" policy language that had appeared in nearly all of the CIAs since 2001, but also reorganized the key provisions and added much more prescriptive detail, in particular related to clinical care and physical plant requirements. For example, the 2014 Foundation CIA required implementation and reporting on capital improvements, and the 2014 Extendicare CIA required a Staffing Review Committee and specific measures to deliver effective rehabilitation services. Of note, the most significant CIA document structural developments in recent CIAs is the addition of key CIA obligations outside of the Policy and Procedures section, where CIAs had previously embedded such specific requirements. For example, the Staffing Review Committee requirement in the Extendicare CIA appears in the primary CIA Obligations section, and prescribes several specific actions that Extendicare management must take to review, respond to, and report on staffing issues.

It is important to note that, while much of the language in each of the CIA documents over the study period is "cut and pasted" from the CIA before it, the implementation of each CIA legal contract is, in part in practice, a negotiation between the SNF corporate management, HHS-OIG, and the CIA Quality Monitor. It is also

critical to appreciate the context in which these CIA negotiations have occurred over the span of the study period, namely, amidst a gradual, though not complete, cultural acceptance of CIAs in the SNF community, and in the context of generally improving quality in the nation's SNFs, and specifically with regard to the pressure ulcer and indwelling catheter use quality measures. It is primarily because of the implementation of the early CIAs and the growing regulatory emphasis on SNF quality of care that the federal government has been able to achieve the more rigorous clinical and staffing requirements in the most recent generation of CIAs.

3. The SNF Corporations' Stated Challenges with CIAs.

Historically, health providers generally, and the SNF industry in particular, have raised certain concerns with CIAs and challenges with meeting CIA requirements.[25] There are four main concerns typically raised by the SNF industry. First, the industry maintains that compliance with CIAs is costly given the time and effort required for compliance, the costs of developing and implementing new policies and procedures, the cost of implementing change across often 'silo-ed' departments within the SNF corporation, the additional staff required to meet CIA requirements, and the cost to the SNF of hiring an IRO and Quality Monitor for a 5-year period. The industry further maintains that the CIA breach and default clauses, and the stipulated penalties that could possibly accrue on a daily basis could be substantial and crippling. Second, the industry maintains that CIA regulations are complex and contain legal terms and requirements that are burdensome, such as the auditing, reporting, and monitoring requirements. Further the industry maintains that there is an ever-growing list of healthcare regulatory requirements

[25] Solution Brief, "Corporate Integrity Agreements," *MetricStream* (May 27, 2014).

including HIPAA[26] and Stark regulations. Third, the SNF industry maintains that the CIA provisions which require Corporate Officers and Senior Managers to certify the effectiveness of SNF compliance programs is challenging because SNFs business units are often scattered across the corporate organization, making it difficult to track and certify the effectiveness of their corporate compliance programs. Finally, the SNF industry maintains that the extensive documentation required to comply with a CIA is overly burdensome, including reporting to OIG, preparing quality assessments, tracking quality risks, and preparing internal reports across multiple departments within SNF corporations and SNFs.[27]

C. Previous Studies of the Effectiveness of Quality CIAs and a CMS SNF Quality Improvement Program.

There has only been one study which assessed (primarily qualitatively) the effectiveness of some components of a quality CIA, and only one other evaluation which assessed a CMS SNF quality improvement program. In 2009, HHS-OIG prepared a report which reviewed 15 SNF chains that began CIAs between June 2000 and December 2005 (2009 HHS-OIG CIA Study). In 2013, Abt Associates, Inc. prepared an evaluation of the CMS quality improvement program – the Special Focus Facility Study (SFF Study).

1. 2009 HHS-OIG CIA Study.

The 2009 HHS-OIG CIA Study had three objectives: (1) to determine the extent to which CIA SNFs implemented required quality of care structures and processes; (2) to

[26] Healthcare Portability and Accountability Act of 1996 (HIPAA)(P.L. 104-191).
[27] *Id.*

assess how responsive these SNFs were to quality monitoring; and (3) to describe the challenges encountered by SNFs when implementing CIA requirements.

The methodology used in this 2009 HHS-OIG CIA Study was to review documents for the 15 SNF corporations, review the SNF Quality Monitors' recommendations, and to review the minutes of the SNF Quality Assurance Committee meetings (2009 HHS-OIG CIA Study). The study methodology also included structured interviews with members of the SNF corporations and with the SNFs' Quality Monitors.[28] *Id*. In this Study, HHS-OIG also computed the means, standard deviations, and medians for 26 quality measures for the national SNF population and for the 15 CIA SNFs for the HHS-OIG study period of January 1999 through December 2007. HHS-OIG also computed a deficiency index score for each SNF during this 1999 to 2007 study period.

The 2009 HHS-OIG CIA Study found that all 15 SNF corporations enhanced quality of care structures and processes while under their CIAs. All 15 SNF corporations monitored their quality of care using standardized data (quality measure and deficiency data), internal self-assessment tools, and by tracking complaints. The HHS-OIG Study found that each of the 15 SNF corporations created or expanded their compliance infrastructure under their CIAs to integrate quality of care mechanisms. *Id*. The Study also found that SNF corporate representatives concluded that CIAs had a positive effect on their corporations. *Id*. Finally, the Study found that 12 of the 15 SNF corporations accepted and acted on the Quality Monitors' guidance from the start of the CIAs, and that

[28] A Quality Monitor is the individual who is hired by a defendant SNF under a quality of care CIA to monitor and assess the SNF's quality improvement process.

the 3 SNF corporations that were initially resistant to the Monitors' guidance did become responsive following HHS-OIG intervention. *Id*.

The 2009 HHS-OIG CIA Study identified several challenges that the 15 SNF corporations found in implementing CIA requirements (which parallel in many respects the SNF industry concerns discussed in **Section B.2**. above): (1) corporations with multiple SNF facilities encountered challenges in ensuring consistency in quality of care systems across all layers of their organizations and across geographic regions; (2) implementation of quality of care systems was inconsistent across various SNFs within a corporate chain; (3) CIAs caused general organizational disruption; (4) SNF staff were resistant to implementation of new protocols; (5) CIAs required an excessive use of staff time to implement CIA requirements; and (6) there was a significant financial cost associated with CIAs. *Id*.

It is significant that this HHS-OIG CIA Study did not investigate or validate the significance of the CIA impact on quality of care, did not investigate or validate the influence of SNF structural factors, including staffing levels, and resident case-mix acuity on CIA impact, and did not determine whether the CIA had any impact on SNF QMs above and beyond unrelated national trends in SNF QM averages (2009 HHS-OIG CIA Study).

2. <u>The CMS SFF Study</u>.

The 2013 CMS Special Focus Facility (SFF) Study evaluated the CMS SFF Program and made recommendations for SFF Program improvements. The CMS SFF Program was implemented by CMS in 2005 to improve the performance of SNFs with a track record of substandard quality of care and was intended to increase the monitoring

and enforcement of regulations in these SNFs that had consistent histories of noncompliance. (CMS SFF Study, 2013). Noncompliance was determined based on deficiency citations. *Id*.

Once a SNF has been designated as a SFF, the intervention that CMS institutes is that the state surveyors conduct twice the number of standard surveys that the state survey system would otherwise conduct for non-SFF SNFs and increase the potential penalties for poor survey outcomes. States report to CMS on the progress of these SFF SNFs and these SNFs either graduate from the SFF Program or they are terminated from participation in the Medicare and Medicaid programs. *Id*. Graduation requires that SNFs have two consecutive standard surveys without serious deficiencies. The objective of the 2013 CMS SFF Study was to assess how SFF SNFs differ from non-SFF SNFs and to examine underlying conditions in the SFFs that impact the SFFs' ability to comply with federal healthcare quality regulations (CMS SFF Study, 2013).

The 2013 CMS SFF Study found that SFF SNFs are more likely to be for-profit facilities and tend to be larger than non-SFF facilities. *Id*. The Study also found that the successful steps that SFFs took to graduate from SFF status were: staff education and retraining, staffing changes, increased frequency of staff meetings, and increased attention to quality assurance and quality improvement. *Id*. The Study ultimately concluded that staffing changes were the most critical change that SNFs made to improve quality outcomes and to graduate from SFF status. The primary effective staffing changes were eliminating staff that did not embrace the quality culture and onboarding additional staff at the leadership level to support the quality culture. *Id*. Of particular relevance to my study is that this 2013 CMS SFF CMS Study found that once a SNF

graduated from the SFF program, relapse on surveys and obtaining survey deficiencies was common. *Id*.

3. Evidence Related to SNFs' Characteristics that Make these Entities Amenable to Quality Improvement.

The literature supports that there are a number of SNF characteristics that predict whether a SNF will adopt the required processes and achieve sustained quality improvement (Rantz, et al., 2012). These characteristics include: (1) a leadership team dedicated to learning how to use QM reports as a foundation for improving resident care and outcomes; (2) members of the leadership team who can be a change champion to ensure that QM reports are created and circulated monthly to all key SNF units; (3) a leadership team that is willing to involve all staff in the facility in educational activities to learn about the QM process and the reports that show how the SNF compares with other SNFs in the state, region, and nationally; (4) a leadership team willing to plan and continuously educate new staff about the MDS and federal QM reports and how to engage in quality improvement activities; and (5) a leadership team willing to continuously involve all staff in quality improvement committee and team activities so that the staff can "own" the new processes and are responsible for change. *Id*.

D. History of Federal Regulation of this Nation's SNFs and Recent Proposed Amendments to SNF Regulations.

Poor SNF quality of care has been a national concern since the U.S. Senate Special Committee on Aging first began hearings in 1963. Reports about poor quality continued into the 1980s and led to an Institute of Medicine (IOM)(1986) report on widespread quality problems and recommendations for stronger federal regulations of this nation's SNFs (Harrington, et al., 2004). In its 1986 report, the IOM found that "care

in the nation's nursing homes was shockingly deficient." (IOM, 1986). The IOM Report lead to passage of major nursing home reform legislation – the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987). OBRA 1987 strengthened SNF quality standards, the CMS state survey system and data collection, and enforcement mechanisms for SNF regulation.

OBRA 1987 also required the creation of resident care plans using the Resident Assessment Instrument (RAI) and the Minimum Data Set (MDS) (Wan, et al., 2006). The original MDS was developed in 1990, implemented in 1991, and was redesigned as MDS 2.0 in 1995.[29] (Castle et al., 2010). From its inception, the MDS was intended to serve multiple purposes: to collect data to both inform care plans and describe the resident population, to generate QMs to evaluate SNFs and guide improvement interventions, and to serve as a data source for SNF payment systems. (Ranham, et al., 2009). Starting in 1998, SNFs were required to electronically submit MDS data to CMS. (Ranham, et al., 2009). In 2002, the CMS Nursing Home Compare website was launched. *Id.* In October 2010, MDS 3.0 was implemented nationally.

In 2010, the Affordable Care Act (ACA) expanded quality of care requirements for SNFs that participate in the Medicare and Medicaid programs. The ACA incorporated the Nursing Home Transparency and Improvement Act of 2009 which was enacted because SNF complex ownership and management structures were inhibiting regulators' ability to hold SNF chains accountable for regulatory violations. The ACA

[29] The MDS 2.0 is a 284-item instrument devised to evaluate the medical, mental, and social characteristics of SNF residents. The MDS measures residents' ADLs as well as changes in those ADLs. The MDS is divided into 15 sections: cognitive patterns, communications and hearing patterns, vision patterns, physical functioning and structural problems, continence, psychosocial well-being, mood and behavior patterns, activity-pursuit patterns, disease diagnoses, health conditions, nutritional status, oral and dental status, skin condition, medication use, and special treatments and procedures.

also incorporated the Elder Justice Act and the Patient Safety and Abuse Prevention Act, which included provisions to protect SNF residents from abuse and other financial crimes. Under these new laws, SNFs now faced more stringent standards regarding disclosure of financial relationships and costs, reporting requirements for nurse staffing, and improvements to compliance and ethics programs. The ACA also mandated that SNFs develop and implement state-of-the-art quality assessment and assurance programs. (Dellefield, et al., 2013).

On July 13, 2015, CMS posted proposed regulations to revise the Requirements for Participation for SNFs in federal healthcare programs.[30] The proposed regulations were published in the Federal Register on July 16, 2015, with a 60-day comment period that was extended. The goal for CMS' proposed amendments was to modernize the SNF participation requirements which had not been comprehensively reviewed since 1991.

These CMS proposed regulations seek to: (1) ensure that SNF staff is properly trained on caring for residents with dementia and in preventing elder abuse; (2) ensure that SNFs take into consideration the health of residents when making decisions on the skill level and number of staff a SNF needs to properly take care of its residents; (3) ensure that SNF staff members have the right skill sets and competencies to provide person-centered care to residents (taking the resident's goals of care and preferences into consideration); (4) improve care planning, including discharge planning for all residents with involvement of the facility's interdisciplinary team, giving residents information they need for follow-up, and ensuring that instructions are transmitted to any receiving facilities or services; (5) allow dietitians and therapy providers the authority to write

[30] *See* 80 Fed. Reg. 41267 (July 16, 2015).

orders in their areas of expertise when a physician delegates the responsibility and state licensing laws allow for this delegation; (6) require SNFs to provide greater food choice for residents; (7) update the SNF's infection prevention and control program, including requiring an infection prevention and control officer, and an antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use; and (8) strengthen the rights of nursing home residents, including placing limits on when and how binding arbitration agreements may be used.[31]

Critics of these CMS proposed regulations maintain that CMS failed to address the "single most significant cause of poor care in nursing homes – staffing" (Harrington, et al., 2015). Critics maintain that CMS rejected numerous requests to promulgate specific mandatory minimum staffing ratios for SNFs. Critics also maintain that CMS should have mandated that an RN is required to be in a SNF 24 hours a day, as opposed to the current 8 hour per day requirement. Critics also argue that training requirements should have been expanded for SNF nursing staff, in particular related to dementia care. Finally, critics argue that residents and caregivers should have been more explicitly and directly involved in the care planning process. *Id*.

E. The CMS Regulatory Process Related to SNF Surveys and Data Collection.

SNFs are subject to quality regulation at both the federal and state levels. Following OBRA 1987, SNFs were required to comply with certain new data collection provisions in order to receive payments from Medicare and Medicaid (Kaiser Commission on Medicaid and the Uninsured, June 2013). Two key new provisions were:

[31] "HHS proposes improved care for nursing homes and residents," located at http://www.hhs.gov/about/news/2015/07/13/hhs-proposes-to-improve-care-and-safety-for-nursing-homes-residents.html#, accessed on December 5, 2015.

(1) the requirement that SNFs prepare regular resident assessments, and (2) that SNFs undergo annual state surveys to ensure compliance with federal regulations related to staffing and quality of life. *Id*. Specifically, SNFs are now required to develop detailed care plans that describe a resident's medical, nursing, and psychosocial needs and describe how the SNF will meet the resident's needs. Care plans are required to include measurable objectives and timetables and be customized to each particular resident. (Levinson, OIG Report November 2012). To develop these care plans, SNFs use the MDS 2.0 or 3.0 electronic forms to assess the resident's clinical condition, functional status, and expected and actual use of services. SNFs submit MDS forms to CMS and CMS uses this MDS data in their Nursing Home Compare (NHC) dataset. The NHC dataset uses QMs to reflect how a SNF is performing in several domains of care quality, such as pressure ulcer prevalence and indwelling catheter use. QMs are facility-level SNF quality measures computed by CMS from resident assessment data (the MDS) that SNFs routinely collect on all residents at specified intervals during their stay (Zinn, et al., 2005). All of the QM measures are defined as rates of positive or negative health outcomes. Some QMs are adjusted to account for differences in case mix across SNFs. *Id.*

As a condition of participation in the federal healthcare program, SNFs are subject to surveys. A SNF is subject to an initial survey by a state survey and certification agency, and then the SNF is surveyed not less than every 15 months while it is in operation. *Id*. Surveys can be conducted more often than every 15 months if it is necessary to determine if SNFs have corrected deficiencies, if there are substantial changes in management or reorganization, or if there were complaints related to

substandard care at the SNF. *Id*. State surveys involve on-site inspections for compliance with about 175 federal regulatory requirements which include observation, review of facility and resident records, and interviews with residents, staff, and family members. *Id*. Data from these surveys are compiled to create CMS' OSCAR database. [32] OSCAR contains data on facility, staff, and resident characteristics, and on deficiencies related to SNF quality.

F. Changing Nature of the SNF Industry and SNF Residents over the Study Period.

1. Changing Nature of the SNF Industry During the Study Period.

In the 1990s, SNF chains[33] grew steadily in numbers and emerged as the dominant organizational form for skilled nursing facilities. A number of SNF chains were publically-traded companies until the early 2000s when five of the largest SNF chains declared bankruptcy (Harrington, et al., 2012). After the restructuring and ownership changes in the industry in the early 2000s, and with increases in Medicare payments, the largest SNF chains became more financially stable through the 2000s. *Id*. From 1994 to 2004, the annual rate of SNF ownership conversions tripled. (Grabowski et al., 2008). Specifically, there were 108 SNF for-profit to government conversions, 153 government to for-profit conversions, 219 non-profit to government conversions, and 251 government to non-profit conversions. *Id*. A detailed discussion of the specific SNF

[32] The Online Survey, Certification and Reporting system (OSCAR) is a data network maintained by CMS in cooperation with the state long-term care surveying agencies. OSCAR is a compilation of all of the data elements collected by state surveyors during inspection surveys at SNFs and NFs for the purpose of certification of participation in the Medicare and Medicaid programs. OSCAR is the most comprehensive source of facility-level information on the operations, patient census, and regulatory compliance of SNFs and NFs. OSCAR data is collected on each facility annually. CASPER is a computer application used by CMS for the OSCAR data.

[33] A SNF is part of a chain if the same corporate entity operates more than one SNF.

conversion numbers for CIA and non-CIA SNFs during my study period from 2003 to 2015 is located in **Chapter 4, Section B.2**.

By 2008, SNF chains made up 54% of the nation's SNFs (Harrington, et al., 2012). Since 2010, the ten largest SNF chains have accounted for 14% of the industry market (Harrington et al., 2014). Very recently, some of the largest publically-held SNF chains were purchased by private equity investment firms; therefore the owners of the SNFs are separated considerably from the clinical care process. (Harrington et al., 2015).

From 2009 to 2014, the total number of SNF beds declined slightly and reached 1.6 million in 2014 (with an average of 109 beds per facility) (Harrington et al., *The Kaiser Commission on Medicaid and the Uninsured*, 2015). SNF occupancy rates declined in this 2009 to 2014 period from 83.7% in 2009 to 82.3% in 2014. *Id*. Over this period, the percentage of SNFs that were for-profit increased slightly from 67% in 2009 to 69% in 2014, while the share that were not-for-profit declined slightly from 26% in 2009 to 24% in 2014. *Id*. The government-owned SNFs remained at about 6% during this timeframe. *Id*. More than 50% of the SNFs over this period were owned or leased by chains having two or more facilities. Medicaid is the primary payer source for most nursing facility residents receiving skilled care. In 2014, more than 63% of facility residents had Medicaid as the primary payer. (Harrington et al., *The Kaiser Commission on Medicaid and the Uninsured*, 2015).

In 2014, the total nursing hours (RN plus LPN plus CNA) averaged 4.0 hours per resident day which marked an increase from 3.9 in 2009. *Id*. However, there was wide state variation in average nursing hours per resident day (HPRD) and national-wide a large percentage of the 4.0 HPRD were accounted for by non-licensed nursing care. *Id*.

Between 2009 and 2014, the average number of health deficiencies[34] per facility declined from 9.33 to 7.96 and the number of facilities with no deficiencies increased. *Id*. In 2014, deficiencies were most commonly given for failures in infection control, quality of care, and unnecessary drugs. In 2014, more than one in five facilities received a deficiency for actual harm or jeopardy for a resident. *Id.*

2. Changing Nature of SNF Residents During the Study Period.

From 2009 to 2014, SNF residents' acuity has been fairly stable. (Harrington et al., *The Kaiser Commission on Medicaid and the Uninsured*, 2015). During this time period, resident' level of need for assistance with ADLs scored 5.8 on a scale from 3 to 9. Residents on average had mobility impairments, which ranged from difficulty walking to the inability to get out of bed. In 2014, only 4% of residents were bed bound, but 64.3% of residents depended on wheelchairs for mobility or were unable to walk without extensive support from others. *Id*. In 2014, 76% of residents received special skin care related to pressure ulcer treatment or prevention and 6% of residents nationally were documented to have pressure ulcers, down from 6.5% in 2009. *Id.* In 2014, 5.7% of residents used an indwelling catheter, down from 6.1% in 2009. *Id*.

In 2014, nearly half of SNF residents had a dementia diagnosis. (Harrington et al., *The Kaiser Commission on Medicaid and the Uninsured*, 2015), and 31% had other psychiatric conditions such as schizophrenia, mood disorders, or other diagnoses. *Id.* Nearly two-thirds of residents received psychoactive medications including anti-depressants, anti-anxiety drugs, and anti-psychotics. There has been a welcome decline

[34] Health deficiencies are assigned by state surveyors to SNFs who fail to meet any of the 175 process or outcome federal regulatory requirements.

in the use of physical restraints with residents and in 2014, the percentage of residents subject to physical restraints was down to an all-time low of 2%. *Id*.

G. Regional Variation in SNF Quality.

There is regional variation in SNF quality and in the stringency of regulatory enforcement of SNF regulations at the state level. The relationship between location and SNF quality is linked to: regional differences in resident characteristics, care practices, the cost of delivering care, and reimbursement rates. (O'Neill et al., 2003). These differences are also linked to inconsistency among surveyors in measuring deficiencies in different regions. *Id.* Notably, a high percentage of low-performing SNFs are in the South (Louisiana, Mississippi, and Georgia) (Mor, et al., 2004).

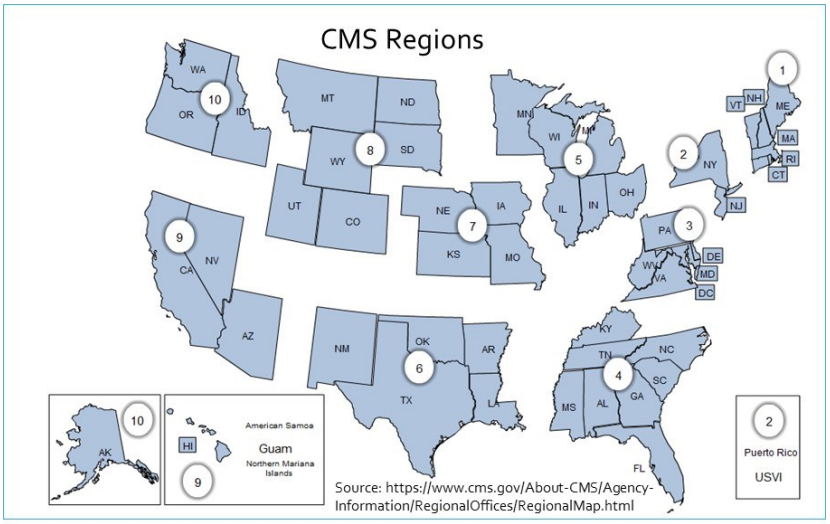
SNFs also have different characteristics across the various regions. SNFs in the East have larger facilities and higher occupancy rates while SNFs in the Midwest have the smallest facilities (Harrington et al., *The Kaiser Commission on Medicaid and the Uninsured*, 2015). SNFs in the Southeast have higher shares of residents with Medicaid as their primary payer. *Id*.

Ownership patterns of SNFs vary widely across states. (Harrington et al., *The Kaiser Commission on Medicaid and the Uninsured*, 2015). In 2014, Alaska, Hawaii, Indiana, and Wyoming had greater than 30% of their facilities that were government-owned. More than 50% of facilities in Alaska, Washington, DC, Minnesota, North Dakota and South Dakota were non-profit facilities. In 2014, more than 80% of facilities in Alabama, Arkansas, Arizona, California, Oklahoma, Oregon, and Texas were for-profit. *Id*.

There is also a wide variation in state staffing levels, ranging from 3.6 HPRD in New Mexico to 5.3 HPRD in Alaska. *Id.* There was also a wide variation across states in the average number of deficiencies per facility, ranging from 2.27 deficiencies in Rhode Island to 19.26 deficiencies in Washington, DC. Finally, there was variation in the share of facilities with no deficiencies (ranging from 30.95% in Rhode Island to no facilities in Alaska, Washington, DC, Hawaii, and Wyoming). *Id.*

There is a variation in the stringency of regulatory enforcement across the states because the SNF industry is truly decentralized to the states. (Harrington et al., 2014). A study of state SNF regulatory enforcement action using a summary of five indicators of enforcement stringency found that regulatory enforcement varied widely across the states. (Harrington, et al., 2004). Some of the states with poorest SNF regulatory enforcement records were primarily in the plains, Rocky Mountains, and the north western states, which are located in six of the ten CMS Regional offices. *Id.* See **Figure 2.1** below for a map of the CMS Regions.

Figure 2-1 – CMS Regions



Many factors have led to variations in enforcement across the states, including: underfunding of the regulatory system in some states, political influence of the SNF industry, and social, economic, and political environmental factors across the states. (Harrington, et al., 2014). Some states in the lower-performing quartiles also cite a lack of support from CMS regional offices for their failure to implement intermediate sanctions. (Harrington, et al., 2004). Because of theses regional differences, residents experience differing levels of quality care across the states and therefore have different QM based on the state and CMS region where the SNF is located. *Id.*

H. Pressure Ulcer and Indwelling Catheter Use QMs are Reliable, Valid, and Accepted Measures of SNF "Quality."

The Institute of Medicine (IOM) has defined quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." (Castle, et al., 2010, *citing* IOM, 1996). Outcome quality measures are considered more stringent quality indicators than structure or process QMs because deviations from appropriate care protocols will likely influence residents' health outcomes. *Id.* The two NHC QMs that were used in my study were developed through rigorous and extensive testing that included both provider and consumer concerns of what indicators were most useful in determining measures of SNF quality. *Id.*

1. Pressure Ulcer and Indwelling Catheter Use QMs are Strong Indicators of SNF Quality.

Certain QMs are considered significant indicators of SNF quality, including pressure ulcer and indwelling catheter use QMs (Hillmer, et al., 2005, Palmer, 2008, Burfield, et al., 2012; Bell et al., 2013). These QMs represent two important aspects of

resident outcomes: skin integrity and bowel/bladder status (Wan, et al., 2006). There is support in the literature that pressure ulcers, in particular, are a strong marker of quality of care because very few SNF residents receiving proper care should develop pressure ulcers or have pressure ulcers worsen while in a facility's care. (Hillmer, et al., 2005).

While no one overall indicator of SNF quality exists, pressure ulcer and catheter use QMs are strong proxies for SNF quality (Castle, et al., 2011). Castle et al. used both long-stay pressure ulcer and catheter use QMs in his studies because, "of all the QMs available for study, these specific long-stay QMs were thought to be the most sensitive to quality of care processes as well as to staffing levels." *Id*.

2. The Two Study QMs have Strong Reliability and Validity.

Researchers have found that the best national data sources for SNF quality are the CMS Nursing Home Compare (NHC) QM data, based on the MDS, and the OSCAR database, which have acceptable reliability and validity. (Bostick, et al., 2006). NHC Quality Measures, and pressure ulcer and catheter use QMs in particular, are reliable, valid, and an accepted measure of SNF quality. (Mor, et al., 2011, Zhang, et al., 2009, Sangl, et al., 2005, Kash, et al., 2009). HHS-OIG quality Monitors and many corporate compliance departments commonly use NHC QMs as indicators of SNF quality (2009 HHS-OIG CIA Study, Castle, et al., 2010).

The reliability and validity of the Minimum Data Set (MDS (2.0)) on which the NHC QMs are primarily based have been deemed acceptable by many researchers (Mor, et al., 2011, Zhang, et al., 2009, Sangl, et al., 2005). The inter-rater reliability of the NHC QMs shows almost perfect agreement for many measures and substantial agreement

for most items (Sangl, et al., 2005). All measures exceeded 0.65.[35] Specifically, the two QMs used in this study, have been validated and tested by researchers (Kash, et al., 2009). The evaluation testing of MDS 3.0 indicated that it had even increased measurement accuracy, reliability, and validity from MDS 2.0 (Saliba, et al., 2008, Ranham, et al., 2010). [36]

3. Stratification and Risk Adjustment in the Study.

This study includes a stratified QM (pressure ulcers) and includes risk adjustment for each SNF based on the SNF's aggregate resident case-mix acuity. First, the QM for pressure ulcers is stratified by high-risk and low-risk residents, and the QM that has been used in this study is specifically for long-stay high-risk residents. A resident is considered high risk if the MDS report indicates that the resident is impaired in transfer or bed mobility, that the resident is comatose, or if the resident suffers malnutrition as defined in the relevant MDS ICD-9 scores.[37] Low-risk residents are all residents that are not high-risk (and this low-risk category is not part of this study).[38] The indwelling catheter use QM is not stratified based on high and low-risk residents.

Second, when examining SNF quality using QMs, a risk adjustment is often used based on the aggregate acuity level of the SNF residents (Castle, et. al., 2007). Since health outcomes are the result not only of quality of SNF resident care but also of the SNF residents' risk factors, outcome-based quality measures must account for differences in the case-mix of resident risks across providers[39] (Mukamel, et al., 2008). Risk

[35] In particular, for the pressure ulcer QM, the kappa is 0.74.
[36] MDS 3.0 made some changes to pressure ulcer measurements in particular. In the change from MDS 2.0 to 3.0, MDS 3.0 eliminated pressure ulcer reverse staging and added whether a pressure ulcer was present on admission to the SNF (Ranham, et al., 2009).
[37] For both MDS 2.0 and MDS 3.0 measurements.
[38] *Id.*
[39] Throughout this study, "providers" refer to SNFs.

adjustment controls for resident case-mix acuity. *Id*. In my study, resident case-mix acuity has been added to my statistical model used in Research Objective Two in order to isolate the influence of SNF resident case-mix acuity on the effect of a CIA on the two QMs at issue.

4. Determining Thresholds for the Two QMs.

Kane et al., pointed out that in SNF care, acceptable standards and thresholds of performance must be established to define and assess quality (Kane, et al., 1998). In 1996, a SNF expert panel convened and determined thresholds for 13 NHC QMS, and pressure ulcers and indwelling catheter use were included in the analysis. The panel re-convened in 1998 and slightly revised its 1996 threshold determinations. The expert panel determined that a good threshold for percentage of SNF residents with pressure ulcers (Stage 1 to 4) was 2.4 % and a poor threshold was 7.7% and above. (Rantz, et al., 2000). Today, the target threshold for high-risk residents with a Stage II to IV pressure ulcer is 5%.[40] The 1998 panel further determined that a good threshold for percentage of residents who have used an indwelling catheter was 2.1% and a poor threshold was 6.5% and above (Rantz, et al., 2000).

5. Some Limitations of the MDS QMs.

NHC QMs have certain limitations and raise some threats to validity. First, no single QM represents the overall quality of care provided by a SNF (Castle et al., 2010). Second, process and outcome QMs can be vulnerable to detection or ascertainment bias. *Id*., (Sangl et al., 2005, Arling et al., 2005). For example, higher quality SNFs may be more capable of making assessments about quality measures than lower quality SNFs

[40] Interview with Dr. Sue Renz on July 6, 2015.

(Castle, et al., 2010, Arling et al., 2005). Higher quality SNFs may be looking for problems whereas lower quality SNFs may have high staff turnover or high agency use and have basic problems with documentation and consistency. *Id*. Higher quality SNFs may have systematically higher QM rates and lower SNFs may have systematically lower rates. *Id*. Third, the MDS on which the QMs are based, and the OSCAR/CASPER system on which SNF resident case-mix acuity levels are based are self-reported and not audited by a third party (Zhang, et al., 2009). One study found that variation among SNFs in MDS measurement errors was due to state differences, implying that there were state-level factors that had an impact on measurement error (Wu, et al., 2009). SNFs in states with more stringent survey processes and policies may under-document adverse events to avoid sanctions (paper compliance). *Id.,* (Ranham, et al., 2009). SNFs in states with a case mix-based reimbursement system may have a higher incentive to over-report conditions that lead to more reimbursement. *Id.*

Some threats to validity to the MDS include having different raters fill out the MDS and the random error associated with the fact that MDS coordinators in different SNFs have varying levels of education and training (Shin, et al., 2009). This interrater variation could threaten validity. Some researchers have maintained that the reliability of the MDS may be threatened by residents' unstable health and functional status where some MDS assessments (cognitive function or pain) may fluctuate due to acute events or medication schedules. *Id.* While this reliability issue may apply for more subjective assessments, this limitation is unlikely to apply for pressure ulcer and catheter use detection. *Id*. In sum, despite these limitations, studies have consistently found MDS

and OSCAR data to be consistent and reliable. (Zhang, et al., 2009, Shin et al., 2009, Sangl, et al., 2005).

I. Evidence-based Protocols Exist for Preventing SNF Pressure Ulcers and Reducing the Use of Indwelling Catheters in SNFs.

Scientific evidence has shown that use of evidence-based clinical protocols can improve pressure ulcer and indwelling catheter use rates in long-stay residents in SNFs. Over the CIA period, CIA quality Monitors assess CIA SNFs for use of these evidence-based protocols to improve their pressure ulcer and indwelling catheter use rates.

1. The Problem of Pressure Ulcers in SNFs and the Evidence-Based Protocols to Achieve Improved Quality.

Pressure ulcers in SNFs are a significant quality problem that has not appreciably improved over time.[41] Pressure ulcers are commonly used as an indicator of quality because they correlate closely with lack of attention from SNF staff and because they are an important measure of resident health (Landi, et al., 2007). Untreated pressure ulcers often lead to complications including cellulitis, chronic infection and osteomyelitis. *Id*. Care for residents at risk of developing or with pressure ulcers requires SNF staff to reposition residents several times each day; for this reason, an increase in LPN and CNA time typically correlates with a decrease in pressure ulcers (Horn et al., 2005).

Nationally, average SNF pressure ulcer prevalence ranges from 2% to 24% (Qaseem, et al., 2015). Smaller studies based on direct observation of SNF residents, report prevalence of pressure ulcers as high as 28% at some SNFs.[42] Given that, in 2014, pressure ulcer prevalence was 6% nationally, and that the United States SNF population

[41] Pressure ulcers are defined as localized injury to the skin and/or underlying tissue, usually over a bony prominence as a result of pressure alone or a combination with shear. (Qaseem, et al., 2015).
[42] National Nursing Home Improvement Collaborative: Pressure Ulcer Prevention and Treatment Handbook (October 2003) at 17.

is approximately 1.6 million residents, this translates to more than 96,000 SNF residents who have at least one pressure ulcer at any point in time during their SNF stay.[43] Between 1990 and 2001, pressure ulcers were reported as a cause of death in nearly 115,000 residents. (Qaseem, et al., 2015). The estimated cost in treating each case of pressure ulcers ranged from $20,900 to $151,700, (Yap, et al., 2015), and the cost of treating pressure ulcers nationally has been projected up to $1 billion annually (Horn, et al., 2010).

Studies indicate that there has not been significant improvement in pressure ulcer prevalence and incidence due, in large part, to SNFs' failure to adhere to evidence-based practice guidelines such as the Agency for Healthcare Research and Quality (AHRQ) clinical practice guidelines for pressure ulcer assessment, prevention, and treatment[44] or as the clinical guidelines from the American College of Physicians and Surgeons (Qaseem, et al., 2015). One study found that SNFs varied significantly in adherence to evidence-based pressure ulcer prevention guidelines, ranging from 29% to 52% overall adherence (Saliba, et al., 2002).

SNF studies have shown that following the AHRQ clinical practice guidelines and use of specific clinical pathways, systematically reduced the prevalence and incidence of pressure ulcers.[45] **Figure 2-2** below shows the AHRQ pressure ulcer clinical pathways.

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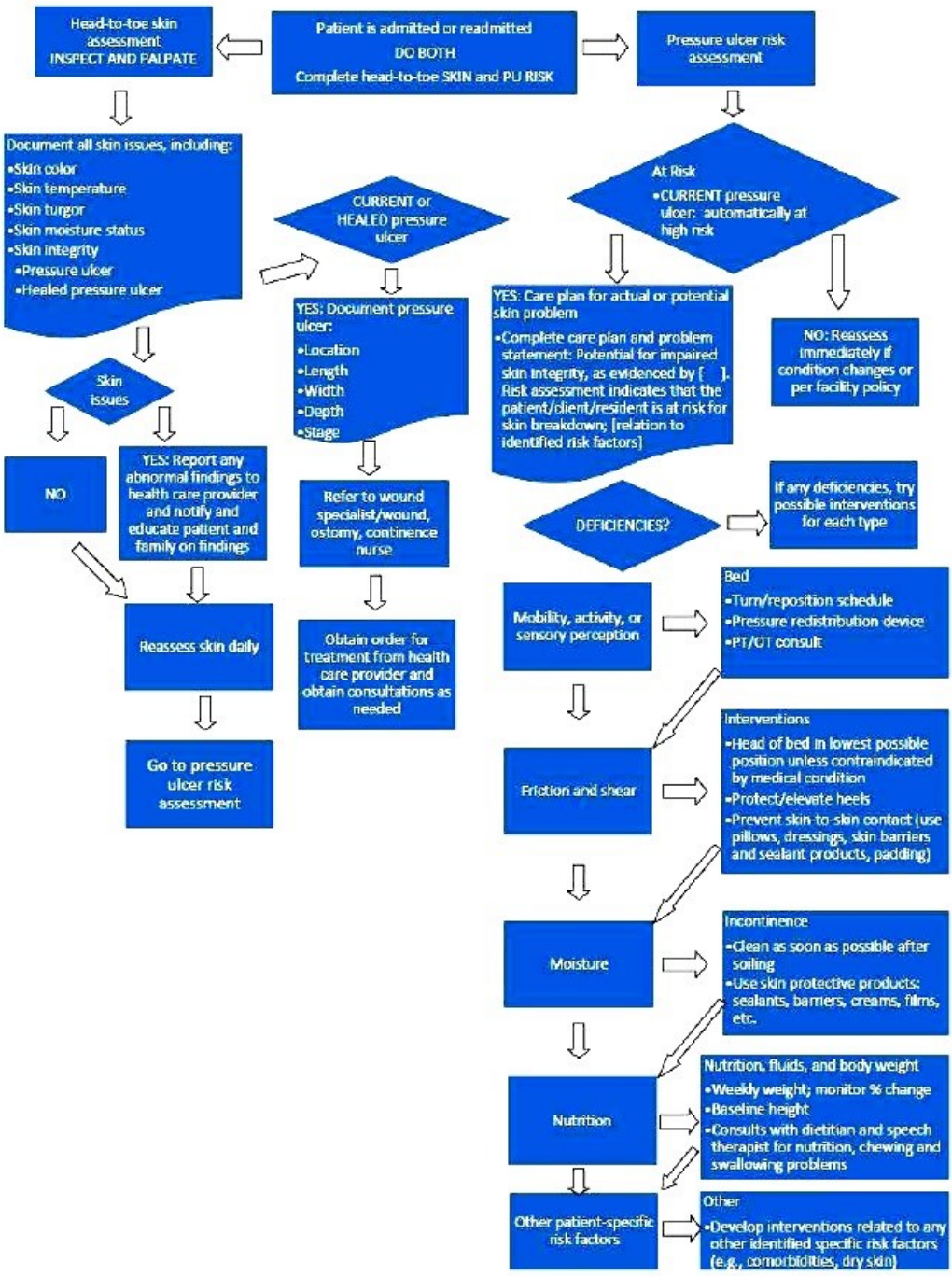
[43] *Id*.
[44] The AHRQ Clinical Practice Guidelines for Pressure Ulcer Prevention and Treatment are found at: http://www.ahrq.gov/professionals/systems/hospital/pressureulcertoolkit , accessed on December 17, 2015.
[45] *Id., supra* note 41, *c*iting a study demonstrating a reduction in the six-month incidence of pressure ulcers from 23% to 5% in a single facility; reporting an 87% and 76% reduction in the incidence of pressure ulcers among high-risk residents in two SNFs; and reporting a 42% reduction in pressure ulcer prevalence over four years after implementation of a quality improvement program using evidence-based protocols in a long-term care facility.

Figure 2-2 – Pressure Ulcer Clinical Pathways[46]



[46] This clinical pathways Figure was located at http://www.ahrq.gov/professionals/systems/hospital/pressureulcertoolkit, accessed on January 2, 2016.

These evidence-based guidelines for pressure ulcer prevention and treatment begin with accurate risk assessment. The recommended evidenced-based risk assessment tool for predicting pressure ulcer risk is the Braden Scale (Bergstrom et al., 1998.)[47] This evidence-based tool for risk assessment requires an assessment upon admission, and then 24 to 48 hours later after admission. Reassessment is then required weekly for the first 4 weeks after admission, and monthly to quarterly thereafter; reassessment is also required after a significant change in health status.[48]

Key processes of care for pressure ulcer prevention and treatment include establishment of a realistic individualized care plan based on risk assessment, daily skin assessment, management of pressure ulcers by proper positioning and repositioning residents every 2 to 3 hours, using pressure reducing surfaces such as advanced static mattresses, ensuring pressure relief of heels for all at-risk residents while in bed, ensuring appropriate nutrition, hydration and pain management, and monitoring the SNF's management of pressure ulcers (AHRQ clinical practice guidelines, Qaseem, et al., 2015, Berlowitz, et al., 2003.) The evidence shows that once a resident obtains a Stage III or IV pressure ulcer, the specific treatment methods that most quickly heal this stage of pressure ulcer are: sufficient enteral feeding when this is the only way to provide sufficient nutrition, the use of soap and water or saline to cleanse the wound, and moist dressings (Bergstrom, et al., 2005). Additional evidence-based protocols included involvement of leadership and multi-disciplinary teams in the pressure ulcer prevention

[47] This Scale is a rating scale made up of six subscales scored from 1-4 (1 for low level of functioning and 4 for the highest level or no impairment). Total scores range from 6-23 (one subscale is scored with values of 1-3, only). The subscales measure functional capabilities of the resident that contribute to either higher intensity and duration of pressure, or lower tissue tolerance for pressure. A lower Braden Scale Score indicates lower levels of functioning and therefore, higher levels of risk for pressure ulcer development.
[48] *Id.*

and treatment process, ongoing staff education and sustained audit and feedback for promoting accountability and recognizing success for pressure ulcer prevention and treatment (AHRQ clinical practice guidelines, Sullivan, et al., 2013).

Key factors which contribute to the development and persistence of pressure ulcers in residents include age, immobility, inadequate nutrition, device-related pressure, and dehydration (Qaseem, et al., 2015, Baharestani, et al., 2007). High rates of pressure ulcers in SNFs have a number of causes: understaffing, high levels of staff turnover, lack of appropriate durable medical equipment use, including failure to use appropriate support surfaces, failure to prepare appropriate care plans (Berlowitz, et al., 2003), poor certified nurse aid (CNA) documentation, and failure to adhere to evidence-based guidelines in pressure ulcer assessment, prevention and treatment (Horn et al., 2010).

In general, the barriers to the use of evidence-based pressure ulcer guidelines in SNFs can be categorized into: (1) SNF organizational factors; (2) lack of education and training; (3) lack of SNF resources; and (4) complexity of design and wording of the evidence-based guidelines. Of note, the scientific evidence shows that resources and staffing are a significant reason why the guideline to reposition residents every two hours is not adhered to (Berlowitz, et al., 2003, Colon-Emeric, et al., 2007). For example, for a SNF with 50 at-risk residents, evidence-based guidelines would require 600 turns each day, 18,000 each month, and 216,000 each year. *Id.*

2. The Problem of Indwelling Catheter Use in SNFs and the Evidence-Based Protocols to Achieve Improved Quality.

Studies indicate that 40% of all indwelling catheters[49] used are not necessary in SNF residents and hospital patients. (Robinson, et al., 2007). Studies further indicate that 8.5%-10% of all residents or patients who have indwelling catheters develop catheter-associated urinary tract infections (CAUTIs), which account for at least 40% of nosocomial infections in these care settings. *Id*. The most important risk factor for development of a CAUTI is the duration of catheterization. A low percentage of residents become infected during the first 3 to 5 days of catheterization whereas residents who have a catheter in place for 7 to 10 days have a rate of infection of 10 to 40%. *Id*. A resident who has a catheter inserted for 14 days or more is likely to develop an infection that is resistant to antibiotics. *Id*. Urinary catheter-related infection leads to an almost three-fold increase in risk for death, independent of other co-morbid conditions. *Id*. The Centers for Disease Control (CDC) advocate avoiding use of urinary catheters in SNF residents for management of urinary incontinence.[50] In addition to infection, other bad outcomes can occur with catheterization such as urethral erosion, hematuria, abscesses, pain, and obstructions. Indwelling catheters further impair functional status as residents with indwelling catheters are more confined. *Id*.

As Robinson et al. found "clearly the most appropriate intervention [to avoid preventable harm to residents] is to insert urinary catheters only for specified reasons and then remove them as soon as possible." (Robinson, et al., 2007.) Evidence-based

[49] An indwelling urinary catheter is a drainage tube that is inserted into the urinary bladder through the urethra, is left in place, and is connected to a closed collection system.
[50] Centers for Disease Control, Catheter Use, located at http://www.cdc.gov/HAI/ca_uti, accessed on August 28, 2015. *Id*.

protocols for the reduction of indwelling catheter use in SNFs begin with staff education.[51] First, this protocol calls for SNF staff to be educated that the following residents do not benefit from indwelling catheters: (a) those who cannot communicate their need to void; (b) those who are incontinent; (c) those who are hemodynamically stable; and (d) those who have urinary retention that can be managed by other means. *Id.* (*citing* Newman, 2006). The second step in the evidence-based protocol to reduce catheter use is for SNF nurses to be educated to request a physician's order for removal of a resident's catheter unless it is being used for one of the following nine reasons: (1) bladder irrigation; (2) relief of urinary tract obstruction; (3) drainage for a resident with a bladder that cannot be managed by any other means or type of catheterization; (4) to obtain accurate intake and output in critically ill residents; (5) as an aid in urological surgery; (6) ordered by a urologist for a designated special purpose; (7) for management of urinary incontinence in persons with a Stage III or IV ulcer of the coccyx; (8) comfort care in terminally ill residents; and (9) residents within 48 hours of surgery. *Id.* A third step in the evidence-based protocol to reduce catheter use involves ongoing monitoring of indwelling catheter incidence and prevalence (Willson, et al., 2009), and finally, careful attention to techniques for catheterization and catheter care. *Id*.

In a study in Iowa using the NICHE catheter-reduction evidence-based protocol, the mean number of days that residents' catheters were in place was reduced from 8.57 days to 4.5 days, and 66.7% of the resident catheters were removed in less than 4 days. (Robinson, et al., 2007.) In this study, nurses improved from asking for a physician's order to remove the catheter 43% of the time to making this request 93% of the time. *Id*.

[51] This evidence-based protocol was developed by the Nurses Improving Care to Health System Elderly (NICHE) group.

Also in this study, use of the evidence-based protocol resulted in all but 6% of the residents' catheters being removed before discharge. *Id*.

Clearly, there are clinical pathways to improve SNF QMs related to pressure ulcers and indwelling catheter use. In many cases, SNFs that are subject to CIAs will be required by their Quality Monitors to follow these evidence-based protocols with the goal to improve QM outcomes.

J. CMS Guidance and Quality Improvement Initiatives During the Study Period Related to Pressure Ulcer Prevention and Reduction of Indwelling Catheter Use.

During the study period, from 2003 to 2015, CMS issued new guidance and rolled out several quality improvement initiatives related to pressure ulcer prevention and the reduction of indwelling catheter use. In 2005, CMS issued new guidance to surveyors on pressure ulcers. This new guidance had several additional requirements for SNF surveyors: (1) the guidance mandated risk assessment for pressure ulcers on every resident on admission, including a complete body check for pressure ulcers; (2) the guidance mandated a pressure ulcer treatment plan; (3) the guidance mandated increased pressure ulcer documentation; (4) the guidance mandated physician involvement in pressure ulcer care; and (5) the guidance also focused on assessment of whether the pressure ulcer was avoidable.[52] Also in 2005, CMS issued new guidance to surveyors on indwelling catheter use which mandated that a resident who enters a SNF without an indwelling catheter not be catheterized unless the resident's condition demonstrates that catheterization is necessary. This guidance specifically required: (1) an initial resident assessment for the resident at risk for catheterization; (2) an ongoing assessment of the

[52] Pressure Ulcer Regulations in the Nursing Home: Introduction to Revised F-tag 314 (June 2015).

resident's continued risk; and (3) implementation and monitoring of any individualized interventions for effectiveness.[53]

In 2006, CMS instituted the Advancing Excellence Campaign.[54] Advancing Excellence is a voluntary coalition of providers with the goal of promoting excellence in SNF care. The Advancing Excellence Campaign offers training related to evidence-based pressure ulcer prevention protocols. In 2008, CMS also focused on SNF quality through the Special Focus Facility (SFF) Initiative. SNFs that have a greater number of quality problems, more serious problems than average, and demonstrated patterns of quality problems are included in the Initiative. Many SNFs in the SFF program focus on improving prevalence of pressure ulcers and indwelling catheter use. In 2008, CMS also began intensive work with state Quality Improvement Organizations (QIOs) to generally improve SNF quality at the state and regional levels. (Ranham, et al., 2010). The QIOs were made up of a multi-disciplinary team of physicians, nurses, and SNF administrators working together to improve quality of care. The QIOs also provided technical assistance and tools and shared best practices with SNFs across the nation.[55] The QIO program has specifically focused on pressure ulcer prevention and reduction. *Id*.

In 2011, the QIOs established partnerships with stakeholders and residents and formed Learning Action Networks (LANs). The LANs have aligned their efforts with the Agency for Healthcare Research and Quality and the Centers for Disease Control and Prevention to focus on quality and specifically on pressure ulcer issues. *Id*.

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[53] CMS Guidance on Indwelling Catheter Use, dated April 14, 2015.
[54] CMS Advancing Excellence Campaign, located at https://www.nhqualitycampaign.org/, accessed on December 1, 2015.
[55] CMS Quality Improvement Organizations, located at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/index.html?redirect=/qualityimprovementorgs/, accessed on December 5, 2015.

K. The Effect of Certain SNF Structural Characteristics on SNF Quality of Care: For-profit status, Payer-Type, Occupancy Rate, and Acuity.

Scientific evidence suggests that certain SNF structural characteristics have an effect on SNF quality of care. These characteristics include for-profit status, payer type, occupancy rate, and acuity (Castle, et al., 2007, Grabowski, 2001).

Several recent studies indicate that the nation's largest for-profit SNFs deliver significantly lower quality care than non-profit SNFs, as measured by QMs. (Harrington et al., 2014, Kash, et al., 2009, Shippee, et al., 2015, Xing, et al., 2013). In 2005, Hillmer, et al., conducted a comprehensive literature review of 38 studies from 1990 to 2002 which concluded that quality was lower in for-profit SNFs (Hillmer, et al., 2005). In particular, Hillmer, et al. found that the rate of pressure of ulcers was higher in for-profit SNFs. *Id*. Studies of ownership conversions of SNFs show that facilities converting from non-profit to for-profit status were generally declining performers, while facilities converting from for-profit to non-profit facilities were generally improving performers (Grabowski, et al., 2008).

A recent study by Harrington, et al., showed that the ten largest for-profit SNF chains had residents with higher acuity, lower nursing staff levels, and higher numbers and more serious violations of federal quality regulations compared to not-for-profit and government-owned SNFs (Harrington, et al. 2012). According to Harrington, the largest SNF chains have a business strategy of keeping labor costs low to increase profits which sacrifices quality of care (Harrington et al., 2011). Extreme levels of profit-taking are significantly associated with poorer quality. (O'Neill, et al., 2003).

Additionally, a 2011 GAO Report found that SNFs that were for-profit or owned by private investment firms were more likely to have deficiencies than not-for-profit

facilities (GAO Report, July 2011). The evidence shows that not-for-profit SNFs have better QM outcomes and fewer deficiencies than for-profit SNFs (Xu, et al., 2013, Commodore, et al., 2009, Hillmer, et al., 2005).[56]

Another SNF factor that is associated with quality of care is payer type. SNFs with a higher Medicare census, and with more Medicare resident days are associated with better QM scores (Kash, et al., 2009, Shippee, et al., 2015). There is a relationship between Medicaid occupancy and poorer SNF QM scores, where the higher percentage the Medicaid occupancy, the worse the QM scores (Grabowski et al., 2004, O'Neill, et al., 2003, Xing, et al., 2013). The evidence shows that nursing facilities providing skilled care that serve a predominantly Medicaid population have fewer nursing staff, lower occupancy rates, and more health-related deficiencies. (Mor, et al., 2004). This disparity in quality is likely due to variation in reimbursement rates because nursing facilities providing skilled care get reimbursed at a significantly lower rate for Medicaid residents than they do for Medicare residents (O'Neill, et al., 2003).

Medicaid payment rates are established by states with formulas that result in lower reimbursement rates relative to other payers (Decker, et al., 2008). Medicaid rates are tied to the fiscal status of states where fiscal crises introduces uncertainty for nursing facilities about future Medicaid rates. *Id.* Dependence on Medicaid results in limited disposable income for the nursing facilities and uncertainty about future revenue levels which limits investment to improve future resident care. *Id.* Studies have also linked Medicare/Medicaid status to staffing levels. A high proportion of Medicare residents

[56] In the United States, approximately 70% of SNFs are for-profit facilities, 25% of SNFs are not-for-profit facilities, and the remaining are government-owned facilities (CRS Report 2014). Over half of all SNFs in the United States are owned by chains or corporations that own multiple facilities (Kaiser Report, June 2013).

predicted higher staffing hours and a higher proportion of Medicaid residents predicted lower staffing hours. (Harrington, et al., 2003). Studies have further found that RN staffing levels decreased among both for-profit and not-for-profit facilities when Medicaid census increased and Medicaid payments decreased (Decker et al., 2008, Harrington et al., 2007). Further research shows that facilities that are more resource dependent on Medicaid reimbursement appear reluctant to hire more staff of all types (Harrington et al., 2007).

Another SNF factor, occupancy rate, is associated with SNF quality of care in that higher-occupancy facilities report better QM scores. (Decker, et al., 2008, Zinn, et al., 2005). In the case of predominantly Medicaid nursing facilities providing skilled care, at low occupancy there are fewer residents to account for fixed costs so a greater proportion of resident revenue has to cover fixed costs. Lower occupancy implies greater dependence on a facility's revenue sources. Therefore the lower the occupancy rate, the less likely nursing facility management will invest in resident care. (Decker et al., 2008).

A final SNF factor associated with quality of care is resident case-mix acuity. A higher resident case-mix acuity has been associated with poorer SNF QM scores (Kash et al., 2009, Wan, et al. 2006). Studies have shown that the case mix of residents was a positive predictor for RN hours but yet was a negative predictor for total staffing hours. The theory here is that SNFs take resident case mix into account for registered nursing hours but do not consider acuity in planning total nurse staffing levels. This approach could result in inadequate total hours for residents in a SNF with high care needs where total nurse staffing levels are lacking. (Harrington et al., 2007).

L. The Effect of Staffing on SNF Quality of Care, Including Debate Surrounding a Federal Mandatory Minimum Nurse Staffing Level.

1. Increased Nurse Staffing Levels Improve SNF Care Quality.

The preponderance of the evidence from several research studies led the Institute of Medicine to conclude that there is a positive relationship between staffing and quality of SNF care (IOM, 1996). In fact, as early as the 1970s, it has been shown that there is a relationship between higher RN hours and total nurse staffing hours per resident day (HPRD) and improved resident outcomes (Harrington, 2005). SNF residents are characteristically frail and are highly dependent upon staff for their physical, mental, and social needs, in many cases for many years. (Grabowski, et al., 2007). The scope and duration of residents' dependence on staff likely predispose resident health outcomes to a high degree of sensitivity to the composition of SNF staff. *Id*.

Current research shows that SNFs with higher levels of nurse staffing have better performance, as do SNFs with higher skilled nursing staff ratios (Xing, et al., 2013). High nurse staffing hours have been associated with improved care and resident outcomes for functional abilities, pressure ulcers, weight loss and other measures of quality (Harrington, et al., 2014, Bostick et al., 2006, Castle, 2008, and Hyer et al., 2011). A higher RN staffing mix has been associated with fewer pressure ulcers and less catheterization (Konetzka et al., 2008). The direct link between RN staffing mix and quality outcomes may occur because staffing patterns influence the amount of time RNs can devote to direct patient care as well as supervising and mentoring other nursing staff (Weech-Maldonado, et al., 2004). RNs have a significant role in nursing homes in that they provide direction and evaluation of care provided by LPNs and CNAs. They provide clinical knowledge, care coordination, and professional oversight (Castle, et al.,

2011). Kane et al., found that SNFs where nursing leaders are educated at a master's degree or higher levels had lower rates of pain, catheter use, and UTIs, after adjustment for SNF size. (Kane, et al., 2003). Therefore, higher RN staffing mix facilitates greater utilization of RN's clinical expertise, which leads to improved quality outcomes. *Id*.

Evidence consistently shows that low nurse staffing levels and untrained staff are considered the highest predictors of poor SNF quality (Harrington, et al., 2011, Weiner, et al., 2007), and that increases in RN staffing are likely to reduce adverse outcomes in some SNFs (Hyer, et al., 2009, Konetzka, et al., 2008). Studies show that SNFs with low staffing levels, particularly low RN levels, have high rates of poor outcomes on indicators such as pressure ulcers, catheterization, lost ability to perform ADLs, and depression (Chen, et al., 2015). Of note, pressure ulcer QMs are one of the most sensitive QMs linked to staffing (Bostick, et al., 2006).

Further, increased use of agency or temporary staff has been strongly associated with lower quality care (Castle, et al., 2011). Inadequate care processes lead to poor resident outcomes while well-trained nurses who use evidence-based practices such as positioning and good catheter care lower mortality and increase the chance of discharge from a SNF. (Wan, et al., 2006).

2. <u>For-Profit SNFs Typically Have Lower Nurse Staffing Levels</u>.

Studies show that from 2003 to 2008, the large for-profit SNF chains had fewer nurse staffing hours than not-for-profit chains, when controlling for other factors. (Dellefield, et al., 2015). While these for-profit chains had the sickest residents, their total nursing hours were 30% lower than not-for-profit SNFs. *Id.* Further, in 2013, the nation's 12 largest SNFs were well below the national average for RN HPRD and total

nurse staffing levels. *Id.* Lower staffing levels, particularly RN staffing, translate into lower labor costs, which could likely be a management strategy by the large chains to reduce overall SNF operating costs (Harrington, et al., 2012).

3. Recent Federal Legislation Mandating a New Source of SNF Staffing Data.

To date, the sources of SNF staffing data have been self-reported CMS MDS and OSCAR data, and state-level self-reported data. However on October 6, 2014, legislation was enacted which in the future could greatly improve the quality of the SNF staffing data available to CMS and to researchers. The Improving Post-Acute Care Transformation Act of 2014 (IMPACT Act) requires SNFs, by 2016, to report nursing staff levels, skill mix, and turnover data based on personnel records that will be auditable as opposed to self-reported, unaudited data. (Dellefield, et al., 2015).

4. Evidence Supports a Mandatory Federal SNF Staffing Minimum of 4.1 HPRD.

Following OBRA '87, a number of states introduced legislation to establish or increase mandatory minimum staffing standards using either minimum staffing levels or minimum staff-to-resident ratios (Chen et al., 2015). By 2003, 36 states had supplemented the OBRA laws with mandatory minimum staffing guidelines and today all 50 states have mandatory minimum staffing regulations. **See Appendix C for a listing of all states' specific mandatory minimum nurse staffing standards.** However, despite CMS studies supporting a federal mandatory minimum, to date, CMS has not established a federal mandatory minimum staffing level for SNFs.

In a well-publicized 2002 Report to Congress, CMS found "strong and compelling statistical evidence" that SNFs with a low ratio of nursing staff to residents

were more likely to provide substandard care and recommended a minimum staffing level of 4.1 hours of care per resident day.[57] CMS' analysis identified staffing thresholds that maximize quality outcomes and concluded "quality is improved with incremental increases in [total] staffing up to the identified [4.1 hours per resident day] threshold." *Id.* The CMS minimum nurse staffing threshold was confirmed by Schnelle, et al., in 2004. The Schnelle, et al., study examined the differences in quality of care processes among selected California nursing homes stratified with different staffing levels during a three-day site visit using standardized protocols to independently assess 16 care processes (Schnelle, et al., 2004). SNFs in the upper 10th percentile on staffing (> or = 4.1 HPRD) performed significantly better on 13 of 16 care processes. *Id.* Residents in the highest staffed homes were significantly more likely to be out of bed and engaged in activities during the day and receive more feeding assistance and incontinence care *Id*. In a national study of 35 SNFs serving United States veterans, residents in SNFs with staffing levels of 4.13 HPRD experienced a 3% lower rate of pressure ulcer development (assuming a 1.6 million SNF population, this translates to a reduction in pressure ulcers for 48,000 residents (Collier et al., 2008).) Even more conservative than the CMS recommendation was the recommendation of the Harrington geriatric panel which recommended 4.55 HPRD (Kim, et al., 2009) in order to achieve quality SNF care.

Many studies have found that higher state minimum staffing standards for nursing homes have a positive effect on improving actual nurse staffing levels and on quality outcomes (Bowblis, 2011; Harrington, et al., 2007, Hyer, et al., 2009, Mukamel, et al., 2012). However, the findings are complex in that the existing literature generally

[57] CMS (2002) "Appropriateness of Minimum Staffing Ratios in Nursing Homes," Report to Congress. Baltimore: Centers for Medicare and Medicaid Services.

suggests that while overall nurse staffing levels have increased in response to minimum staffing standards, this response has largely resulted in a lower nursing skill mix as SNFs have responded to these broad staffing standards by hiring more CNAs and LPNs, as opposed to higher cost RNs. Given that the average cost of an LPN to a SNF is 74% of the cost of an RN, and the cost of a CNA is 42% of the cost of an RN, SNFs have decided to invest in more, lower-cost staff when faced with mandatory state minimum requirements (Chen, et al., 2015).

Evidence also suggests that SNFs decrease indirect care staff in the context of minimum direct care staff standards, including indirect care workers in the areas of housekeeping, food service, and activities staff. *Id.* While the majority of studies show a modest positive quality response to the staffing standards specifically as defined by survey deficiencies and contractures, other quality measures such as physical restraints, antipsychotic medications, pressure ulcers and catheters remained unchanged. *Id.* Finally, the literature has shown that the effects of mandatory minimum staffing is strongest in those facilities that had the lowest staffing at baseline (Chen, et al., 2015, Park et al., 2008).

Currently, while SNFs are not subject to a federal mandatory minimum number of nurse staff, under OBRA '87, SNFs are required to: employ an RN as the Director of Nursing (DON), and RNs as the assistant DONs and educational coordinators in larger facilities and to have at least one RN on duty for no fewer than 8 hours per day, 7 days per week. In facilities with fewer than 60 residents, the DON may serve as the one RN on duty; have either an RN, a licensed practical nurse (LPN), or licensed vocational nurse (LVN) on duty for the evening and night shifts; and are required to have "***sufficient***

nursing staff to provide nursing and related services to attain and maintain the ***highest practicable physical, mental, and psychosocial well-being of each resident***."

5. Current Developments and Debate Related to a Federal Mandatory Minimum Nurse Staffing Level and the New Proposed CMS Regulations.

The literature supports the finding that there are pros and cons to mandatory minimum SNF staffing laws. Critics of minimum staffing have raised several issues with minimum staffing policies. (Chen, et al., 2015). Some critics are generally against policies that do not allow providers to choose the most efficient mix of inputs in the production of care. *Id*. Other critics argue that because prices in healthcare are often set administratively, SNFs will be unable to raise output prices to account for the increased labor costs under minimum staffing standards (Chen, et al., 2015). There is concern that minimum staffing standards may take resources away from other areas of the SNF such as indirect care staff or facility infrastructure. (Bowblis, et al., 2013). A final criticism of the minimum staffing policies is that they are often not adequately enforced because of the cost burden that the regulation places on providers and the severe nursing shortage in some local markets (Chen, et al., 2015). For example, evidence shows that in 2003, 27% of SNFs failed to comply with their states' minimum staffing standards. *Id*.

The proponents of minimum staffing respond to these critiques directly. First minimum staffing proponents rely on the literature which states that the lower level of resident care resulting from insufficient staffing can be more expensive than maintaining higher staffing levels (adding staff can improve continence care and can lead to gradual dose reduction in the use of antipsychotics which reduces product costs and costs related to injuries from related infections and falls) (Rudder, et al., 1998, Hughes, et al., 2000).

Since July 2015, following CMS' release of their proposed regulations, debate has intensified regarding the need for CMS to require a federal minimum staffing standard for SNFs. Proponents of this mandatory federal minimum staffing requirement argue that the minimum requirement for SNF staffing should be at least 4.1 hours of direct nursing care per resident day (HPRD).[58] Proponents of the 4.1 HPRD argue that CMS' proposed regulations only require "sufficient nursing staff with appropriate competencies and skill sets."[59] CMS does not define "sufficient" in this proposed regulation. Proponents argue that with the growth of multistate for-profit SNF corporations and the emergence of private equity firms in the SNF market, the lack of specificity in the CMS regulations will create incentives for facilities to reduce costs by cutting staff. *Id*.

Proponents of the federal mandatory minimum staffing requirements for SNFs also support the 4.1 HRPD based on CMS' 2002 which recommended 4.1 as the "staffing threshold that maximize[es] quality outcomes and where…quality is improved with incremental increases in total staffing up to the identified 4.1 HPRD threshold."[60] Proponents of the 4.1 HPRD threshold also rely on numerous studies (Harrington, et al., 2000, Schnelle et al., 2004)[61] that link this threshold staffing level with improved care quality.

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[58] Letter from Anne Montgomery, Senior Policy Analyst, Altarum Institute to Andy Slavitt, Acting Administrator, CMS (October 12, 2015).
[59] *See* 80 Fed. Reg. 41267 (July 16, 2015).
[60] CMS (2002) "Appropriateness of Minimum Staffing Ratios in Nursing Homes," Report to Congress. Baltimore: Centers for Medicare and Medicaid Services.
[61] *See also*, The Coalition of Geriatric Nursing Organizations, "Research Supports 4.1 HPRD Minimum Staffing Recommendation," (June 27, 2014), located at www.aanac.org/white papers/, accessed on December 5, 2015.

M. Gaps in the Scientific Literature Support the Need for this CIA Study.

This Literature Review underscores the need to address my Three Research Objectives in light of the existing body of literature. There is a clear gap in the scientific literature regarding any studies which investigate or validate the significance of CIA impact on SNF quality of care, investigate or validate the influence of SNF structural factors, staffing levels, and SNF resident case-mix acuity on CIA impact, as well as any studies which determine the significance of any differences between national SNF QM averages and CIA-covered SNF QM averages. Given that the United States government (through the Department of Justice and HHS-OIG) is fundamentally relying on CIAs to improve quality of care in our nation's SNFs, it is critical to understand if this chosen tool is achieving the desired results during the CIA and after the SNF CIA period ends. If not, policy change is needed to improve CIA effectiveness.

Chapter III: Methods.

This Methods Chapter discusses my Three Research Objectives and Hypotheses, Study Design, Analysis Plan, and addresses Human Subject issues. Specifically, this Methods Chapter is divided into seven sections: (1) three research objectives and hypotheses; (2) conceptual framework; (3) study design; (4) data sources and data processing; (5) variables and outcome measures; (6) my analysis plan, which addresses: (a) model and hypothesis testing for Research Objectives One, Two, and Three, (b) telephone interviews with government officials and Quality Monitor experts, and (c) treatment of SNF attrition and missing data during the study period; and (7) human subject issues.

A. *Three Research Objectives and Hypotheses*.

My study had three research objectives. My primary research objective was to examine whether quality of care CIAs had a positive effect on SNF quality of care, as measured by two Nursing Home Compare (NHC) quality measures (QMs)[62] – percent of long-stay high-risk residents with pressure ulcers and percent of long-stay residents who have had an indwelling catheter (both as defined in MDS 2.0 and MDS 3.0). This primary objective examined whether the quality CIAs had a positive effect on SNF care quality over and above any unrelated national SNF quality of care trends. An ancillary research objective was to determine when any CIA effect on these two QMs occurred or persisted – that is, did any CIA effect occur before the SNF officially entered into the CIA, during the CIA period, and/or after the SNF completed the CIA. My hypothesis was that a SNF would improve its two QM scores some time before entering and during

[62] These two QMs are taken from the NHC database called "quality msr.csv" for Quality Measures.

the pendency of its quality CIA, but that the SNF's QM scores would worsen at some point after the CIA expired. I further hypothesized that, for SNF chains,[63] where government investigations and case negotiations leading up to a CIA could take months and even years, and where the SNF chain would be aware that its quality processes were being examined, quality improvements related to CIA negotiations would likely be seen 18 to 36 months before the actual start date and formal commencement of the quality CIA.

My second research objective was to examine how, if at all, certain SNF structural characteristics and SNF resident case-mix acuity influenced the effect of a CIA on SNF quality of care and influenced SNF care quality. My hypotheses related to this second research objective were that: (1) most SNF structural factors would not influence the effect of a CIA on SNF quality of care and would not influence SNF care quality; (2) staffing levels and staffing mix would influence the effect of a CIA on SNF quality of care and would influence SNF care quality in that increased staffing levels and higher proportions of RNs as compared to LPN and CNA staffing would positively influence the effect of a CIA on SNF quality of care; and (3) that SNF resident case-mix acuity would influence the effect of a CIA on SNF quality of care and would influence SNF care quality in that, holding all other factors constant, higher SNF resident case-mix acuity would negatively influence the effect of a quality CIA on SNF quality of care, as measured by the two relevant QMs. An ancillary research objective was to directly examine the effect of a CIA on staffing levels and staffing mix. My hypothesis was that in response to a CIA, SNF corporate leadership would increase staffing levels and

[63] A SNF was considered to be part of a chain if the same corporate entity operated more than one SNF.

improve staffing mix, which in turn would positively influence SNF quality of care. Another ancillary research objective was to develop a recommendation for a federal mandatory minimum nurse staffing level.

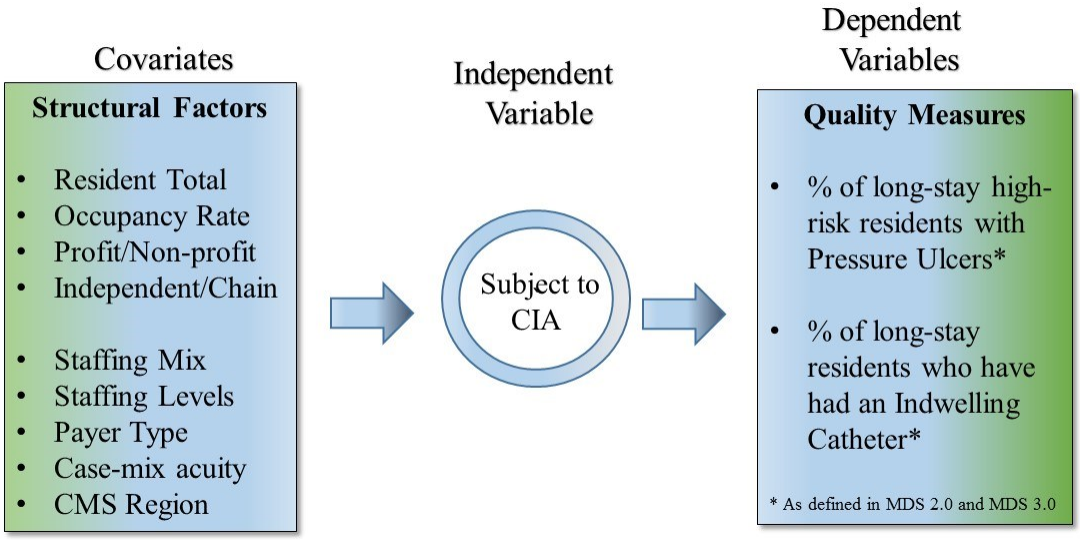
My third research objective was to explore individually the effect of each of the 42 CIAs in this study on SNF quality. Specifically, this objective was to examine the effect of each CIA on SNF quality of care, assessing individual CIA characteristics and their relationship to SNF QMs. This third research objective was also intended to examine specific characteristics of those SNFs that showed QM improvement during any CIA phase. My hypothesis was that individual CIA characteristics would not explain the variance in SNF QM outcomes because the vast majority of CIA requirements were standardized from CIA to CIA. Further, my hypothesis was that staffing level and staffing mix would be most associated with responsiveness of SNFs under CIAs to quality improvement.

B. ***Conceptual Framework***.

My conceptual framework in **Figure 3-1** below depicts the covariates (SNF structural and resident case-mix acuity factors), independent variable, or main predictor, (whether a SNF is subject to a quality of care CIA), and dependent variables (percent of long-stay high-risk residents with pressure ulcers and percent of long-stay residents who have had an indwelling catheter) (both as defined in MDS 2.0 and MDS 3.0) to be evaluated. In addition, two critical identifying characteristics for each SNF were the provider number[64] (to cluster SNF QMs over time) and the CIA number (to cluster SNF QMs into CIA groups).

[64] Throughout this study, "provider" refers to "SNF."

Figure 3-1- Conceptual Framework



C. *Study Design*.

My study design was a secondary data longitudinal analysis of the effect of quality of care CIAs on SNF care quality. My study examined 42 quality of care CIAs covering approximately 1400 SNFs. My study had three research objectives and I used different analytical approaches to address each of the three research objectives.

For my first and primary research objective, I examined SNF provider and QM data before any given SNF entered into a quality CIA (before CIA), during the CIA period (during CIA), and after the SNF completed the CIA term (after CIA).[65] The basic analytic approach was to define a CIA lifespan by generating a categorical variable ***'CIA phase'*** for each time period in the study for each SNF, indicating whether the time period fell before, during, or after the SNF's CIA. For the national SNF quality of care trend

[65] For some CIAs, data were not available for the quarters before the SNFs entered into their CIAs because CMS did not collect and report this data at that time. For other CIAs, data were not available after the SNFs completed their CIAs because the CIAs were still ongoing during the study period or data were missing. In these cases, all available data were used and missing data analyses were performed as described in **Section F.4** of this Chapter.

comparative analysis, SNFs that were not subject to a CIA during the study period were coded with the categorical variable ***'CIA phase'*** as "before" for all study time periods. Then, for each of the two QMs for all approximately 16,000 SNFs nationally, I used mixed effects linear regression analyses to determine if there were statistically significant QM differences across the CIA lifespan, examining the significance and magnitude of the categorical variable ***'CIA phase.'*** My regression model also included a variable to represent ***'time period,'*** so that I could detect any underlying pressure ulcer or catheter use QM trends over the time period of the study from Q4 2003 through to and including Q2 2015.

For my second research objective, I analyzed several covariates, characterizing the influence that factors such as SNF resident total, SNF ownership type, SNF occupancy rate, whether the SNF was independent or part of a chain, SNF staffing levels, staffing mix, payer type, the CMS region where the SNF was located, and SNF resident case mix-acuity have, if any, on the two QMs and on the effect of the CIA on the two QMs. I performed the covariate analyses using mixed effects linear regression, as described below in **Section E.2.b** of this Chapter.

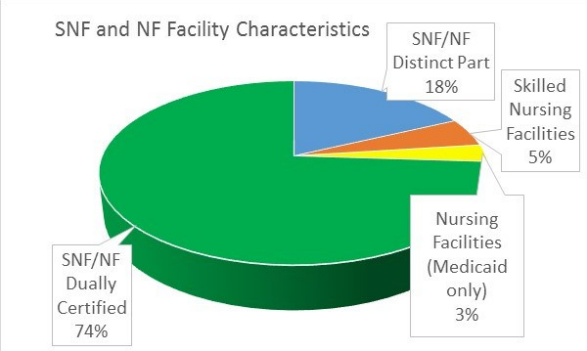
For my third research objective, I sought to understand the effect of individual CIA characteristics on the two QM outcomes. I performed mixed effects linear regression analyses similar to the analysis done in Research Objective One, but for this Third Research Objective, I focused only on the SNFs subject to a CIA, excluding the rest of the SNF population to better examine CIA clustering effects to determine how much variance could be explained by CIAs. For the second component of Research Objective Three, I sought to determine individual CIA characteristics and/or SNF

characteristics that influenced the effect of an individual CIA on SNF quality. Here, I determined which SNFs under individual CIAs showed any QM improvement in any CIA Phase, and then performed logistic regression analysis that compared characteristics of SNFs that improved against SNFs that did not improve in any CIA phase.

1. Study population.

My study population was at the SNF-facility level; I did not study individual SNF residents. The facility selection criteria were: whether a skilled nursing facility (SNF) or nursing facility (NF) was represented in the Nursing Home Compare (NHC) database, and whether the facility provided any skilled nursing care. As depicted in **Figure 3-2** below, of the nearly 16,000 facilities (SNF and NF) in the United States, approximately 97% provided skilled nursing care.[66] For purposes of this study, only nursing facilities that were Medicaid-only and effectively not subject to federal statute and CIAs were excluded from this study (just 3% of facilities.)

Figure 3-2 – SNF and NF Facility Characteristics



[66] **Figure 3-2** was generated from 2003-2011 data downloaded from the Center for Medicare and Medicaid Services (CMS) NHC database. **SNF** and **NF** have been previously defined in the **Chapter 1 Introduction**. "**SNF/NF distinct part**" refers to a portion of a nursing home that is certified to provide SNF services. A 'distinct part' must be physically distinguishable from the larger institution and fiscally separate for cost reporting purposes. The beds in the certified distinct part area must be physically separate from the beds of the institution in which it is located. A "**Dually Certified**" nursing facility refers to a nursing facility having dual certification as a skilled nursing facility and a nursing facility. After 2011, CMS combined the SNF/NF Distinct Part category with the Dually Certified category.

The study population exclusion criteria were: (1) if the facility did not provide any skilled nursing care, (2) if the facility was Medicaid-payer only, and (3) if a SNF was co-located in a hospital. Co-located SNFs were excluded from my study because their structural factors and resident case-mix acuity are not characteristic of the broader non-hospital SNF population.[67] Small SNF QM data were also effectively excluded from my QM analysis because CMS does not publish QM data from SNFs where the denominator of the QM for that SNF is fewer than 30 residents (CMS refers to this process as "low denominator suppression"). There were approximately 2,100 SNFs affected by low denominator suppression during my study period, which means that QM data from those SNFs were not included in my analyses. I examine the impact of that missing data in **Section G.2 of Chapter 4 Results.**

2. Time frame.

The timeframe for this study was Q4 2003 to Q2 2015, inclusive. The study could not begin before Q4 2003 because CMS did not begin to maintain archived QM data on a quarterly basis until the fourth quarter of 2003. Provider data were also available from the NHC database on an annual basis from 2003 through 2015. Finally, OSCAR/CASPER data,[68] used to derive SNF facility-level resident case-mix acuity were available on an annual basis from 2003 to 2015.

[67] *See* (Tyler, et al., 2013, finding that hospital SNFs are not characteristic of the broader SNF population). In practice, hospital-based SNFs are never subject to quality of care CIAs.

[68] The Online Survey, Certification and Reporting system (OSCAR) is a data network maintained by CMS in cooperation with the state long-term care surveying agencies. OSCAR is a compilation of all of the data elements collected by state surveyors during inspection surveys at SNFs and NFs for the purpose of certification of participation in the Medicare and Medicaid programs. OSCAR is the most comprehensive source of facility-level information on the operations, resident census, and regulatory compliance of SNFs and NFs. OSCAR data is collected on each facility annually. CASPER is now the computer application used by CMS for the OSCAR data. Therefore the data is currently referred to as "CASPER" data.

D. ***Data Sources and Processing.***

1. Data Sources.

The sources of data for this study are summarized in **Table 3-1** below.

Table 3-1- Data Sources

Data Type/Element	Source
Covariate	
• **Resident Total**	CMS Nursing Home Compare
• **Occupancy Rate**	Derived from CMS Nursing Home Compare
• **Profit/Non-profit**	CMS Nursing Home Compare
• **Independent/Chain**	CMS Nursing Home Compare
• **Staffing Mix**	Derived from CMS Nursing Home Compare
• **Staffing Levels**	Derived from CMS Nursing Home Compare
• **Payer Type**	CMS Nursing Home Compare
• **Aggregated SNF case-mix acuity**	Derived from OSCAR/CASPER data
• **CMS Region**	Derived from CMS Nursing Home Compare and CMS Regional map
Independent, or Main Predictor	
• **Subject to CIA**	HHS-OIG documentation, CMS data, and research to match corporations under CIAs with their facility level SNFs.
Dependent	
• **% of long-stay high-risk residents with Pressure Ulcers (as defined in MDS 2.0 and MDS 3.0)**	CMS Nursing Home Compare
• **% of long-stay residents who have had an Indwelling Catheter (as defined in MDS 2.0 and MDS 3.0)**	CMS Nursing Home Compare

As indicated in **Table 3-1**, the covariate SNF structural factor data were retrieved from CMS' Nursing Home Compare (NHC) database.[69] Each of the NHC SNF provider records contain: identifying information (e.g., name, address), and structural information (e.g., resident total, profit/non-profit ownership status, staffing labor component

[69] NHC is a publically available web-based system, maintained by CMS, which provides quality information for all Medicare and Medicaid-certified SNFs and NFs in the United States. The quality data are self-reported by the SNFs and NFs, and are not otherwise formally checked for accuracy. NHC contains the facility-level aggregated data obtained from assessment information on a facility's residents using a form called the Minimum Data Set (MDS). During the pendency of this longitudinal study, facilities used both the MDS 2.0 and MDS 3.0 forms to collect their data. The information which is collected on the MDS forms by the SNFs and NFs and provided to CMS includes the residents' health, physical functioning, mental status, and general well-being. The MDS data is used by CMS to calculate the NHC QMs.

information, and payer type). The two dependent data elements, the quarterly QM scores, were also obtained from the NHC data repository. I combined all of the quarterly scores for the two QMs for all the SNFs in the United States from Q4 2003 to Q2 2015 into an Access database for analysis.

NHC quality and provider data were downloaded from the CMS website https://data.medicare.gov/data/nursing-home-compare for Q4 2003 to Q2 2015. CIA information for currently-active quality of care CIAs was gathered from the HHS-OIG website, https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp. OSCAR/CASPER data used to derive the aggregate SNF case-mix acuity score were downloaded from the CMS website https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/. I then merged this aggregated SNF-level resident case-mix acuity data with NHC data in the Access database by provider number and year.

To access non-current archived CIA agreement information, I requested quality of care CIA lists from HHS-OIG and did independent research on Hoovers online service (http://subscriber.hoovers.com.proxy1.library.jhu.edu/H/home/index.html) to trace corporate-level CIA agreements to individual SNF facilities. For the historical CIAs, I researched the various SNFs under given corporate CIAs by using Hoovers to identify CIA corporations and then matched the subsidiary entity information to SNFs in the CMS provider list by name and/or address. I was able to verify this Hoovers research against a comprehensive CMS list provided to me by the CMS Division of Nursing Homes that compiled all individual facility SNFs associated with SNF corporate chains.

For purposes of my study, I calculated aggregated SNF-level resident case-mix acuity as follows: using OSCAR/CASPER data, I obtained average scores for dependency on activities of daily living (ADLs) for each SNF. In doing so, I used the average SNF scores for each of the following three ADLs: (1) eating, (2) toileting, and (3) transferring to and from the bed, chair, wheelchair, or a standing position. The OSCAR/CASPER report had a three-point scale for each of these three ADL categories, where 1 indicated the lowest need for assistance and 3 indicated the greatest need for assistance (and therefore the highest resident case-mix acuity). I computed an average summary score for each ADL for each SNF (with a possible range of 1–3). I then multiplied each summary ADL score by the number of residents in that ADL category for each SNF. I then obtained an average composite score for each SNF by adding each of the 3 scores together and dividing by the total number of residents in each SNF to compute a weighted resident case-mix acuity index score for each SNF ranging from 3–9. This method of calculating aggregated SNF resident case-mix acuity has been relied on in several scientific studies (Grabowski, 2004, Harrington, et al., 2003).

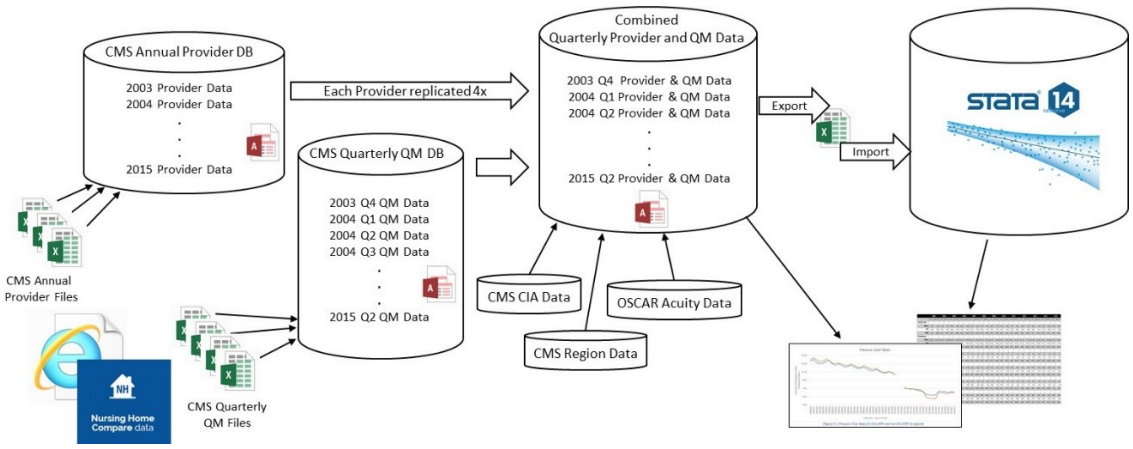
Finally, I derived the CMS Region (1-10) for each SNF provider based on its location on the CMS Region map as shown in **Figure 2-1** in **Chapter 2**.

2. Data Processing.

Figure 3-3 below depicts the data processing approach that I used for this study. Archived CMS provider and QM data were downloaded from the CMS NHC website in Microsoft Excel format and were imported into Microsoft Access (2014 and 2015 provider and QM data were downloaded directly into Access format). Provider and QM Excel files were imported into provider and QM Access database tables. Each annual

provider record was replicated four times to generate the CMS quarterly data needed to match up with the quarterly QM data. This matching by provider number and quarter, the integration of CIA data, CMS region data, and OSCAR/CASPER acuity data, was also accomplished in the Access database. Finally, I exported the data from the Access database and imported the data into the Stata software tool using Excel as a conduit data format. Subsequent statistical analyses were performed using the Stata IC software package, version 14.1 (StataCorp LP, College Station, TX). Most charts were generated using a combination of Access, Excel, and Stata.

Figure 3-3 – Data Processing Model



3. Data Cleansing.

Data cleansing was required in this study related to QM values and staffing level data. CMS typically reports missing SNF QM data with a value of "199", clearly indicating that the value is invalid since it exceeds the maximum 100% QM values. In this study, if the CMS reported value was greater than 100, I converted the QM value to "null."[70] It is noteworthy that according to "low denominator suppression," if a QM for a

[70] Null is equivalent to missing.

SNF has fewer than 30 residents in the denominator for that QM, CMS does not report that particular QM for that SNF.

Through 2012, CMS reported staffing levels using staff full time equivalents (FTEs). After 2012, CMS reported staffing using hours per resident per day (HPRD). For purposes of my longitudinal analysis, I converted the CMS FTE values to HPRD by multiplying the Total FTE * 70 (two 35-hour weeks) and then dividing this product by the total number of days in two weeks (14) and by the total residents. Total FTEs were comprised of RN time (RN Director of Nursing (DON), Nursing Administrator, and RN) plus LPN time, plus CNA time (Medical Aid, Aid, and Aid-in-Training). Full-time, part-time, and contractor time for each of the labor categories were included.

After analyzing this staffing level data it became apparent that some SNFs were likely unclear on how to report staffing levels (especially around the staffing data FTE/HPRD transition period in 2012-2013) because some of the HPRD values were reported in the hundreds. I cleansed the staffing level data by converting any value over 24 HPRD to "null."

4. MDS Measure Conversion.

On October 1, 2010, CMS implemented a new reporting system, replacing Minimum Data Set (MDS) 2.0 with MDS 3.0. While this change may have improved the accuracy of the reported data, the changes also made it more challenging for a researcher to do a longitudinal analysis that spans from MDS 2.0 to MDS 3.0. I have attempted to mitigate this challenge in two ways. First, I selected for my study two QMs that were

implemented in a relatively consistent way between MDS 2.0 and MDS 3.0.[71] Second, I included the MDS version (either 2.0 or 3.0) in my mixed effects linear regression analysis. Including the MDS version in the regression model allowed for the effect of the MDS version to be isolated and evaluated. [72] I have comprehensively examined the peer-reviewed literature to determine how other researchers in longitudinal studies have attempted to bridge the gap between MDS 2.0 and MDS 3.0 data and have not found any examples of this type of longitudinal research to use as a guide.

E. ***Variables and Measures*****.**

1. Dependent Variables.

The dependent variables in this study were the two QM scores selected from the CMA NHC database (percent of long-stay high-risk residents with pressure ulcers and percent of long-stay residents who have had an indwelling catheter). These two QMs are described in detail in **Table 3-2** below. I have included the definition of these QMs for both MDS 2.0 and MDS 3.0 because this longitudinal study spans the MDS 2.0 and 3.0 time period. As noted above, the differences between the MDS 2.0 and MDS 3.0 measures have been accounted for in my statistical models. These two QM outcome variables are measured quarterly, and are considered good measures of SNF quality of care as discussed in **Chapter 2, Section H.1**. [73]

[71] The catheter use QM was essentially the same between MDS 2.0 and MDS 3.0. The pressure ulcer QM did change between the two MDS versions. In MDS 3.0, Stage I pressure ulcers were no longer part of the numerator and reverse staging was prohibited.

[72] **Chapter 4 Results Section C.4** addresses the comparison of Research Objective One results where the MDS version indicator was included in the statistical model to where the MDS QM scores were standardized. This comparison showed that both methods yielded approximately the same results for slope of the relationship between QM scores and CIA phase.

[73] CMS' Division of Nursing Homes Technical Director Dr. Edward Mortimore indicated that these two QMs are strong proxies for SNF quality of care (interview taken via teleconference on July 10, 2015).

It should be noted that clinically, these two outcome QMs are not entirely independent. This is because, in a small number of cases, evidence–based protocols may support maintaining the use of an indwelling catheter if a resident has severe pressure ulcers (Stage III and IV on the coccyx) in order to reduce the incontinence-induced worsening of these pressure ulcers (Robinson, et al., 2007). These protocols may support use of an indwelling catheter until the resident's pressure ulcer has considerably improved (to Stage I or II).[74]

Table 3-2 - Dependent Variables

Quality Measure	Description
MDS 2.0 Pressure ulcers	Percent of long-stay, high-risk residents with pressure ulcers (Stage 1-4) on target assessment that are defined as high risk. Those residents who are considered to be at high risk have one of the following criteria on the target assessment:[75] 1.Impaired in bed mobility or transfer 2.Comatose 3.Suffer malnutrition as indicated by the relevant MDS ICD-9 score
MDS 3.0 Pressure ulcers	Percent of long-stay, high-risk residents with Stage II-IV pressure ulcers. The percent is calculated as follows: ***Numerator*** All long-stay residents with a selected target assessment that meets ***both*** of the following conditions: 1. Condition #1: There is a high risk for pressure ulcers, where "high-risk" is defined in the denominator definition below. 2. Condition #2: Stage II-IV pressure ulcers are present ***Denominator*** Residents are defined as high-risk if they meet ***one or more*** of the following three criteria on the target assessment: 1. Impaired bed mobility or transfer indicated, by ***either or both*** of the following: 1.1. Bed mobility, self-performance 1.2. Transfer, self-performance 2. Comatose 3. Malnutrition or at risk of malnutrition

[74] In addition to the peer-reviewed literature, this clinical analysis was obtained from an interview with a geriatric nurse expert, Dr. Sue Renz, who is also an HHS-OIG CIA Quality Monitor (Interview taken via teleconference on July 6, 2015). Dr. Renz also indicated that pressure ulcer rates and rates of use of indwelling catheters are highly sensitive quality measures for SNFs which are strong proxies for SNF care quality.

[75] A "target assessment or period" is the span of time that defines the QM reporting period (e.g., a calendar quarter).

Quality Measure	Description
MDS 2.0 Indwelling catheter use	Percent of long-stay residents noted to have an indwelling catheter on their most recent assessment.
MDS 3.0 Indwelling catheter use	Percent of long-stay residents who have had an indwelling catheter in the last 7 days. The percent is calculated as follows: ***Numerator*** Long-stay residents with a selected target assessment that indicates the use of indwelling catheters. ***Denominator*** All long-stay residents with a selected target assessment.

2. Main Predictor.

The main predictor (independent variable) in this study was whether or not a SNF was subject to a quality of care CIA.

3. Covariates and Potential Confounders.

As indicated in **Table 3-3** below, I selected several critical structural variables from the CMS NHC data repository to examine as covariates and potential confounders. These included: Resident Total; Occupancy Rate (derived); Profit/Non-profit (or not-for-profit) status; Independent/Chain; Staffing Mix and Staffing Levels (derived); CMS Region; and Payer Type. I also derived aggregated SNF resident case-mix acuity from CMS' OSCAR/CASPER data to examine as a covariate and potential confounder.[76]

Table 3-3 - Covariates

Covariate	Description
Resident Total	Number of Residents
Occupancy Rate	Resident Total divided by the number of federally certified beds.
Profit/Non-profit	Profit status. Non-profit includes government–owned.
Independent/Chain	A SNF is part of a chain if the same corporate entity operates more than one SNF.

[76] I note that there is some overlap in the calculation of the aggregated resident case-mix acuity calculation and in one of the three factors used by CMS to stratify high-risk pressure ulcer residents. As discussed in this Chapter, I have used 'transferring' as one of three ADLs used to calculate acuity, while at the same time, CMS uses transferring in both MDS 2.0 and MDS 3.0 as one of three factors used to determine if a resident is at a high-risk of developing pressure ulcers.

Covariate	Description
Staffing Mix	Ratio of RN Hours per Resident Day (HPRD) to CNA+LPN HPRD. Recorded annually.[77]
Staffing Levels	Total Nurse Staffing in HPRD (CNA+LPN+RN). Recorded annually.[78]
CMS Region	Assigned by CMS according to what state the SNF resides in
Payer Type	Certified in the Medicare Program, Medicaid Program, or both programs.
Aggregated SNF case-mix acuity	Calculated based on CMS' annual OSCAR/CASPER data.

F. Analysis Plan.

This section discusses the explanatory analyses, and the detailed statistical models used to test my hypotheses for each of my three research objectives.

1. Explanatory Analyses.

I performed a number of explanatory analyses to explore and describe my study data.

- **CIA Trends.** I used histograms and stacked bar charts to graph the numbers of CIAs and of CIA-covered SNFs by CIA Phase across the Q4 2003 to Q2 2015 study period.
- **SNF Structural Factors and Acuity.** I created a table showing the mean and number of observations for each of the covariates for each year in the study. I also broke out each covariate for CIA SNFs and non-CIA SNFs, and I used T-tests to explore the statistical differences between the CIA SNFs and the non-CIA SNFs for each covariate.

[77] The specific labor category components that comprise 'RN, LPN, and CNA' are discussed in detail in **Section D.2 of this Chapter.**

[78] Staffing levels are recorded differently in MDS 2.0 and MDS 3.0. In MDS 2.0, staffing levels are recorded in FTEs, whereas in MDS 3.0 staffing levels are recorded in HPRD. I aligned the two recording methods as described above in the Data Cleansing section so that the staffing level measure would be consistent throughout the longitudinal study.

- **QM Explanatory Analysis.** To demonstrate overall SNF secular trends, I graphed the average pressure ulcer and indwelling catheter use QMs for each of the 47 quarters in the study. I also used crude mixed effects linear regression analyses to derive the average change in QM for each time period (the time period slope), and for the change in MDS version.
- **Pressure Ulcer QM Explanatory Analysis.** I graphed the pressure ulcer QM scores for each quarter in the study, breaking out CIA-covered SNFs and non-CIA SNFs and using T-tests to calculate the mean differences between the two groups. I also examined pressure ulcer QM scores by CMS Region and by state. I graphed pressure ulcer QMs by Region and quarter, and then by state and year for the best (lowest QMs) four and worst (highest QMs) four states.
- **Catheter Use QM Explanatory Analysis.** I graphed the catheter use QM scores for each quarter in the study, breaking out CIA-covered SNFs and non-CIA SNFs and using T-tests to calculate the mean differences between the two groups. I also examined catheter use QM scores by CMS Region and by state. I graphed catheter use QMs by Region and quarter, and then by state and year for the best (lowest QMs) four and worst (highest QMs) four states.

2. Model and Hypothesis Testing.

a. Research Objective One – CIA Effect on SNF Quality.

To address my first research objective, to examine whether quality of care CIAs had an effect on SNF care quality over and above any unrelated national SNF quality of care trends, by focusing on pressure ulcer and indwelling catheter use QMs, I used a mixed effects linear regression model, clustering CIAs and SNFs through using a random intercept. These statistical models evaluated the significance and magnitude of the influence of the ***'CIA phase'*** variable (before, during, and after) on SNF care quality. For each SNF, the CIA phase indicated whether the time period was before the SNF entered a CIA, during the CIA, or after the CIA expired. The ***'CIA phase'*** defaulted to "before" for SNFs that were never subject to a CIA during my study period. My mixed effects linear regression statistical model is represented by:

$$Y_{ijt} = B_0 + B_1X_{1t} + B_2X_{2t} + B_3X_{3ijt} + \varepsilon_{ijt} + \gamma_j + \upsilon_i$$

Where:

- Y_{ijt} is the QM Outcome for the i^{th} facility under the j^{th} CIA at time point t
- X_1 indicates Time, by quarter; a number starting at 1 for Q4 2003 and increasing linearly through Q2 2015. (t = 1 to 47)
- X_2 indicates MDS 2.0 ($X_2 = 1$ for MDS 2.0; $X_2 = 0$ for MDS 3.0)
- X_3 indicates the ***'CIA phase'*** and represents the during and post-CIA effects on the QM over and above unrelated national SNF quality trends and the MDS shift
- $\gamma_j \sim N(0,\tau^2)$ is the CIA-specific random effect
- $\upsilon_i \sim N(0,\lambda^2)$ is the SNF facility-specific random effect
- $\varepsilon_{ijt} \sim N(0,\sigma^2)$ is random error

This model "clusters" around CIA and SNF facility Provider Number. Clustering around CIA allows comparison of QM variance between and among CIAs. Clustering around Provider Number reflects the longitudinal nature of the SNF provider data over time and thereby ensures the correct variance calculation.

To assess the appropriateness of including the continuous predictors in my model and to confirm a linear relationship between the predictors and the outcomes, I used an "added-variable" post-estimation plot for each continuous covariate. Compared to simple scatter plots for each individual continuous predictor against the QM outcomes, this added-variable approach had the advantage of showing the adjusted predictor coefficient as the slope of the graphed reference lines.

i. Ancillary Objective One – CIA Impact Timing.

For Ancillary Research Objective One, I investigated whether SNF care quality improvements related to CIA agreements and their associated structure and process changes actually began before CIAs officially took effect. I also investigated whether this potential trend occurred more often in chain SNFs than in single facility SNFs (chain SNFs are defined as a corporate entity that operates more than one SNF). To address this ancillary research objective, I "broadened" my defined CIA coverage period to start up to three years prior to the official start date of the CIA so that more QM observations were included in the "during" CIA phase. This line of analysis attempted to more accurately characterize any quality improvements that were manifest outside of the CIA period, but were in reality related to the CIA effect. My detailed analysis method to address this ancillary research objective was to:

- Utilize the "*chain*" field from the CMS provider files to generate a binary IS_CHAIN variable equaling 1 where more than one SNF was covered by a CIA and equaling 0 where a single SNF was covered by a CIA;
- Generate additional phase variables (e.g., "phase plus 18" and "phase plus 36") by "broadening" the CIA period to start 18 and 36 months,

respectively, earlier than the official CIA start date. Therefore, there were three variables defining phase: one with zero offset from the actual CIA start dates; one with the 'during phase' starting 18 months earlier than the actual CIA start dates; and one with the 'during phase' starting 36 months earlier than the actual CIA start dates. These "phase plus" variables effectively made each CIA look like it had started earlier and had included more QM observations in the 'during phase' instead of the 'before phase;' and

- Re-run the mixed effects linear regression model for each of the two QMs and stratify by IS_CHAIN; using the baseline CIA phase, using the CIA phase plus 18 months, and using the CIA phase plus 36 month variables.

I hypothesized that I could substantiate a correlation between the structural factor of whether a SNF was part of a chain and the length of time prior to the start of the CIA when any quality improvement was manifest. That is, for SNF chains, where the government investigation and potential settlement negotiation typically takes longer and is often more rigorous, I expected the analysis to show a change in the two SNF QMs as much as three years prior to the official CIA start date. In contrast, I expected that CIAs covering individual SNFs would have an impact only when the CIA actually began.

b. Research Objective Two – Covariates and Potential Confounders.

By examining the covariates and potential confounders described above in **Table 3-3**, I assessed how certain SNF structural characteristics and SNF resident case-mix acuity influenced the effect of a CIA on SNF quality of care and influenced SNF care quality. My mixed effects linear regression statistical model is represented by:

$$Y_{ijt} = \beta_0+\beta_1X_{1t}+\beta_2X_{2t}+\beta_3X_{3ijt}+\beta_4X_{4ijt}+\beta_5X_{5ijt}+\beta_6X_{6ijt}+\beta_7X_{7ijt}+\beta_8X_{8ijt}+$$

$$\beta_9X_{9ijt}+\beta_{10}X_{10ijt}+\beta_{11}X_{11ijt}+\beta_{12}X_{12ijt}+\varepsilon_{ijt}+\gamma_j+\upsilon_i$$

Where:

- Y_{ijt} is the QM Outcome for the i^{th} facility under the j^{th} CIA at time point t
- X_1 indicates Time, by quarter; a number starting at 1 for Q4 2003 and increasing linearly through Q2 2015. (t = 1 to 47)
- X_2 indicates MDS 2.0 ($X_2 = 1$ for MDS 2.0; $X_2 = 0$ for MDS 3.0)
- X_3 indicates the 'CIA phase' and represents the during and post-CIA effects on the QM over and above unrelated national SNF quality trends and the MDS shift
- X_4 is Staffing Level,
- X_5 is Staffing Mix,
- X_6 is Case-mix Acuity,
- X_7 is Payer Type,
- X_8 is Profit/Non-Profit,
- X_9 is Resident Total,
- X_{10} is Occupancy Rate,
- X_{11} is Independent/Chain,
- X_{12} is CMS Region,
- $\gamma_j \sim N(0,\tau^2)$ is the CIA-specific random effect
- $\upsilon_i \sim N(0,\lambda^2)$ is the SNF facility-specific random effect
- $\varepsilon_{ijt} \sim N(0,\sigma^2)$ is random error.

By evaluating the statistical significance, direction, and magnitude of each of the variable coefficients reported by Stata, I was able to determine which of these SNF structural factors and acuity were associated with SNF quality of care. Here again, I assessed clustering effects by CIA and Provider Number.

i. Selecting Key Interaction Terms.

I hypothesized that the most critical SNF structural factors that could influence SNF quality were SNF staffing levels, staffing mix, resident case-mix acuity, and whether a SNF was part of a chain. In particular, the staffing level variable represented a structural factor that I expected could modify the effect of these other variables on quality. Of note, staffing level is the first structural factor that many CIA IROs and

Quality Monitors review at the commencement of a CIA. [79] In order to further explore the effect that staffing mix, resident case-mix acuity, and chain status could have on the two relevant QMs at some level of staffing, I created the following interaction terms:

- Staffing Level * Staffing Mix
- Staffing Level * Case-mix Acuity
- Staffing Level * Chain status

The adjusted model with interaction terms is represented by:

$$Y_{ijt} = B_0+B_1X_{1t}+B_2X_{2t}+B_3X_{3ijt}+B_4X_{4ijt}+B_5X_{5ijt}+B_6X_{6ijt}+B_7X_{7ijt}+B_8X_{8ijt}+ B_9X_{9ijt} +$$

$$B_{10}X_{10ijt}+B_{11}X_{11ijt}+B_{12}X_{12ijt} + B_{13}(X_{4ijt}*X_{5ijt}) + B_{14}(X_{4ijt}*X_{6ijt}) + B_{15}(X_{4ijt}*X_{11ijt}) + \varepsilon_{ijt}+\gamma_j+\upsilon_i$$

Where the interaction terms are:

- X4ijt*X5ijt – Staffing level and Staffing Mix interaction
- X4ijt*X6ijt – Staffing level and case-mix acuity interaction
- X4ijt*X11ijt – Staffing level and chain status interaction

ii. Ancillary Objective Two – CIA Effect on Staffing.

To more deeply explore the interrelationships between CIAs and staffing, I pulled the adjusted model apart and performed two mixed effects linear regression analyses with both staffing level and staffing mix as the dependent variables. SNFs cannot directly adjust their QM scores in response to a CIA. However, SNFs can directly adjust staffing levels and staffing mix, with the expectation that increased staffing levels and improved staffing mix ratios will improve QMs. I hypothesized that in anticipation of and in response to a CIA, SNFs would increase staffing levels and improve staffing mix, (which in turn would positively influence QMs). This mixed effects regression model below is

[79] *See* interview with Dr. Sue Renz, dated July 6, 2015, and the relevant peer-reviewed literature summary at **Chapter 2, Section L**.

intended to analyze the relationship between CIA Phase and staffing level and between CIA Phase and staffing mix to test my hypotheses:

$$Y_{ijt} = B_0 + B_1X_{1t} + B_3X_{3ijt} + \varepsilon_{ijt} + \gamma_j + \upsilon_{ij}$$

Where:

- Y_{ijt} is the Staffing Level or Staffing Mix Outcome for the i^{th} facility under the j^{th} CIA at time point t
- X_1 indicates Time, by quarter; a number starting at 1 for Q4 2003 and increasing linearly through Q2 2015. (t = 1 to 47)
- X_3 indicates the 'CIA phase' and represents the during and post-CIA effects on Y_{ijt}
- $\gamma_j \sim N(0,\tau^2)$ is the CIA-specific random effect
- $\upsilon_i \sim N(0,\lambda^2)$ is the SNF facility-specific random effect
- $\varepsilon_{ijt} \sim N(0,\sigma^2)$ is random error.

iii. Additional Ancillary Objective Two – Recommended Federal Mandatory Minimum Nurse Staffing Level.

I conducted a second ancillary staffing level analysis to derive a federal mandatory minimum nurse staffing level recommendation in total nursing HPRD. I determined a staffing level recommendation in two ways. First, I examined the staffing levels for those SNFs that met or exceeded evidenced-based target percentages for pressure ulcers and catheter use for long-stay SNF residents. Scientific literature and CIA Monitors recommended that no more than 5% of high-risk long-stay SNF residents should exhibit Stage II to Stage IV pressure ulcers.[80] Further, the same sources recommended no more than 2.1% of long-stay residents should use indwelling catheters. My methodological approach was to calculate the average staffing level for those SNFs where the percent of high-risk long-stay residents with pressure ulcers was 5% or less, as well as to calculate the average staffing level for those SNFs where the percent of high-risk long-stay residents using catheters was 2.1% or less. For this forward-looking

[80] *See* interview with Dr. Sue Renz, dated July 6, 2015, and **Chapter 2, Section L**.

recommendation, I limited my analysis to QM scores and staffing levels recorded from Q1 2013 to Q2 2015 under MDS 3.0.[81] Second, for purposes of comparison, I calculated a staffing level based on linear regression analysis and model results, using the constant and QM coefficient to generate a target staffing rate.

c. Research Objective Three – Individual CIA Analysis.

I used two distinct methods to accomplish my Third Research Objective, which relied only on CIA SNF data. The first method focused on determining the effect of CIAs on SNF quality using only CIA SNF data in order to determine how much QM variance could be explained by CIAs. Here, I repeated the mixed effects linear regression analysis from Research Objective One, but limited my dataset to just CIA-covered SNFs. It was critical in Research Objective One to include all of the non-CIA SNFs in the analysis to quantify the aggregate impact of CIAs on SNF quality in the context of any national SNF quality trends. By contrast, in Research Objective Three, I wanted to quantify any *differences in QM outcomes between and among* CIAs, and so focusing on just the CIA SNFs eliminated any potential influence of the relatively large number of non-CIA-covered SNFs in the dataset. The goal of this first Research Objective Three analysis was to more clearly examine the CIA clustering effects to ascertain how much QM variance could be explained by CIAs.

The second component of the Research Objective Three analysis focused on assessing how individual quality CIA characteristics and/or SNF characteristics

[81] Given the consistent trend of pressure ulcer QM improvement over the study period from 2003 to 2015, the last three years of QM scores represent a more relevant data set. Further, using only the last three years of CMS staffing data avoids complicating this analysis with the data conversion performed from the MDS 2.0 staffing in FTEs to MDS 3.0 staffing in HPRD. For these two reasons, limiting the staffing analysis to 2013 and after provides a more robust basis for an optimal federal mandatory minimum nurse staffing level recommendation.

influenced the effect of an individual quality CIA on SNF quality of care. My approach to this second component of the Research Objective Three analysis had two steps. First, I pinpointed which CIAs were "successful" in demonstrating QM improvements in either the before-to-during CIA transition or the before-to-after CIA transition. My second step was to perform a logistic regression that compared several characteristics (e.g., staffing mix, staffing levels, resident total, etc.) from SNFs that improved against the same characteristics from SNFs that did not improve, in order to illustrate the attributes of "successful" CIAs.

In the first step of my Research Objective Three analysis I repeated the Research Objective One linear regression analysis for each CIA – *individually*. Although this Research Objective Three approach is limited in some cases by a smaller "n" (for example, many CIAs only covered a single SNF) the CIA-by-CIA analysis still produced many valid results and served to identify several CIAs whose covered SNFs demonstrated improvement in QM scores consistent with my hypotheses. My mixed effects linear regression statistical model for these individual CIA analyses was:

$$Y_{it} = B_0 + B_1X_{1t} + B_2X_{2t} + B_3X_{3it} + \varepsilon_{it} + \upsilon_i$$

Where:

- Y_{it} is the QM Outcome for the i^{th} facility at time point t. (I removed the j subscript representing the jth CIA because each model is limited to a single CIA).
- X_1 indicates Time, by quarter; a number starting at 1 for Q4 2003 and increasing linearly through Q2 2015. (t = 1 to 47)
- X_2 indicates MDS 2.0 ($X_2 = 1$ for MDS 2.0; $X_2 = 0$ for MDS 3.0)
- X_3 indicates the ***'CIA phase'*** and represents the during and post-CIA effects on the QM over and above the unrelated national SNF quality trend and the MDS 3.0 shift
- $\upsilon_i \sim N(0,\lambda^2)$ is the SNF facility-specific random effect
- $\varepsilon_{it} \sim N(0,\sigma^2)$ is random error

I used this CIA-by-CIA linear regression analysis to identify which CIAs showed improvement. A CIA was "successful" in demonstrating improvement if, on average, the QM scores decreased (improved) during either of the two CIA phase transitions for SNFs covered by the CIA. I compared before-CIA QM scores to during-CIA scores and before-CIA QM scores to after-CIA scores. If SNFs under a CIA collectively improved in either of these two CIA phase transitions in a significant way ($p \leq 0.05$) for either pressure ulcer QMs or catheter use QMs, then I assigned a binary flag to that CIA and those SNFs to identify them as "successful." I captured the CIA_PHASE coefficients, constants, and p-values for each CIA and then created a binary variable CIA_IMPROVE to identify those SNFs significantly associated with the expected "successful" QM improvement. If the average SNF QM scores for a given CIA exhibited statistically significant improvement when transitioning from before-to-during or before-to-after, then the binary variable was set to 1 for all of the SNFs covered by that CIA.

i. Ancillary Objective One – Characteristics of SNFs that Improved during any CIA Phase.

In the final step of my Research Objective Three analysis I performed logistic regression for several SNF characteristics (staffing mix, staffing level, payer type, for-profit, acuity, chain status, occupancy rate, and resident total) comparing the SNFs that improved against SNFs that did not improve.

My logistic regression statistical model for this improvement analysis is represented by:

$$Y_i = \beta_0+\beta_1 X_{1i} +\beta_2 X_{2i}+\beta_3 X_{3i}+\beta_4 X_{4i}+\beta_5 X_{5i}+\beta_6 X_{6i}+\beta_7 X_{7i}+\beta_8 X_{8ijt}+ \beta_9 X_{9ijt} +\varepsilon_i$$

Where:

- Y_i is the Improvement indicator for the i^{th} facility
- X_1 is Staffing Level,

- X_2 is Staffing Mix,
- X_3 is Case-mix Acuity,
- X_4 is Payer Type,
- X_5 is Profit/Non-Profit,
- X_6 is Resident Total,
- X_7 is Occupancy Rate,
- X_8 is Independent/Chain,
- X_9 is CMS Region,
- $\varepsilon_i \sim N(0,\sigma^2)$ is random error.

In sum, the two-step approach to Research Objective Three combined the simplicity of the Research Objective One statistical model with the breadth of covariates in the Research Objective Two model in a way that isolated SNF and CIA factors that may have contributed to improved SNF care quality under individual CIAs.

3. Telephone Interviews with Government Officials and Quality Monitor Experts.

From July 2015 through January 2016, I interviewed select government officials and Quality Monitor experts to further inform my discussion and policy recommendations. These experts were CMS Division of Nursing Homes Enforcement Directors and current and former HHS-OIG Quality Monitors. These experts were asked the following questions during their interviews, where relevant: (1) What improvements could be made in the CIA document to assist you in doing your job better as a Quality Monitor? (2) Would more prescriptive CIA language assist you in doing your job better as a Quality Monitor? (3) What other QMs would you study to determine SNF quality other than pressure ulcers and catheter use? (4) Do you think a post-CIA monitoring period would make sense to evaluate how a SNF is performing post-CIA? And if so, how long after the CIA ended would you suggest continuing to evaluate the SNFs under the

CIA? (5) What are all the remedies available to use if a SNF fails to comply with a CIA during the CIA and in the post-CIA period?

4. Treatment of SNF Attrition, Missing Values, and CIA Phase Data Gaps.

Consistent with the imperfect nature of CMS data collection and the realities of the business world, my study dataset exhibits some SNF attrition, missing values, and gaps in the CIA phase information. I followed several approaches to address each challenge.

First, I generated the series of binary variables listed in **Table 3-4** below in order to facilitate the Chi^2 and T-test analyses described below related to SNF attrition and missing values.

Table 3-4 – Generated binary variables used to characterize missing data and its impact

New Variable	Description
UNDER30	= 1 if RESTOT < 30; 0 otherwise
IS_CIA	= 1 if a SNF was subject to a CIA; 0 otherwise
MISSING_ULCER	= 1 if the QM_ULCER value was missing; 0 otherwise
MISSING_CATHETER	= 1 if the QM_CATHETER value was missing; 0 otherwise
DROPOUT	= 1 if a SNF did not report through 2015; 0 otherwise

a. SNF Attrition.

I identified those SNFs lost to attrition by examining the very last time period reported for each SNF: if the SNF reported to CMS during my study period but did not report through the end of my study period in Q2 2015, I determined that the SNF was lost to attrition. To assess the impact of the CIA and non-CIA dropouts, I flagged those SNFs with a new DROPOUT variable and then examined several values for those dropped SNFs as compared to values from SNFs that did not drop out using Chi^2 and T-Tests.

b. Missing Values.

To explore the extent to which missing values might have biased my three research objective results, I examined how "missing-ness" was associated with CIA coverage and SNF resident total. I hypothesized that the majority of the missing QM data was due to the fact that CMS does not report QM data where a SNF's QM denominator has fewer than 30 residents.[82] Using the new variables that I created, I explored the association between SNF resident total and whether data is missing with a series of T-tests and Chi^2 tests.

c. CIA Phase Data Gaps.

This study also had one other type of data challenge because it did not have a traditional "pre-post" design, (where an intervention begins and ends for all participants at the same time.) In fact, as shown graphically in **Figures 4-1 and 4-2** in **Chapter 4**, some CIAs began before the start of my study period in Q4 2003, some CIAs started and ended during the study period, and some CIAs started during the study period but had not ended by Q2 2015. The result is that the data available to compare before, during, and after QMs was asymmetric for any given SNF. To address this challenge I constructed my statistical models (shown above) in as robust a manner as possible. For example, I used the Stata "`mixed`" command to recognize the longitudinal nature of the SNF QM data, clustering on SNF and CIA. I also used a "CIA 0" mechanism (discussed in

[82] CMS encourages SNFs to report QMs even if they have fewer than 30 residents in the denominator for that QM. However, CMS will replace long-stay QM values with "199" if there are fewer than 30 residents represented in the SNF submitted QM denominator. *See* Data Dictionary and data file layout descriptions available at https://data.medicare.gov, accessed on November 25, 2015.

Chapter 4, Section C.3) to incorporate data, where relevant, from all population SNFs and to maximize the regression analysis observations.

G. ***Human Subject Issues.***

This research study has complied with the three main requirements to protect human subjects: informed consent, HIPAA confidentiality of protected health information (PHI), and IRB approval. First, this study does not address issues requiring informed consent and there was no PHI at issue in the study because the data is aggregated to the SNF-facility level. Second, I have obtained an opinion from the Johns Hopkins Bloomberg School of Public Health Institutional Review Board Office (IRB Office) dated November 18, 2015, which concluded that my research study involves secondary data analysis of existing, de-identified and de-linked publically available datasets. The IRB Office determined that this activity would not qualify as human subjects research as defined by DHHS regulation 45 CFR 46.102, and would not require IRB oversight. (A copy of the IRB Office's IRB determination letter is attached in **Appendix D**).

Chapter IV: Results.

This Results Chapter provides an Executive Summary of the study results, a descriptive analysis of the study data, and reports the main findings on each of the three Research Objectives. Specifically, this Results Chapter is divided into seven sections: (1) Executive Summary of the main study findings; (2) descriptive statistics related to CIAs, SNF structural factors and acuity, and explanatory analysis related to national QM secular trends, the percentage of long-stay high-risk SNF residents with pressure ulcers (pressure ulcer QMs), and related to the percentage of long-stay residents who have had an indwelling catheter (catheter use QMs) over the study period; (3) reporting of the main findings of Research Objective One which examined whether quality CIAs had a positive effect on SNF pressure ulcer and catheter use QMs; (4) reporting of the main findings of Research Objective Two which assessed how certain SNF structural factors and case-mix acuity influenced the effect of CIAs on SNF quality of care, including a discussion of interaction results; (5) analysis of and a proposal for a federal mandatory minimum nurse staffing level for this nation's SNFs; (6) reporting of the main findings of Research Objective Three which explored the effect of individual CIAs on SNF quality, and examined the specific characteristics of those SNFs that showed quality improvement under their CIAs; and (7) an analysis of SNF Attrition, Missing Values, and CIA Phase Data Gaps.

A. *Executive Summary of the Main Findings of this Study*.

The results for Research Objective One, to assess whether quality CIAs had a positive effect on SNF quality of care, were that CIAs did not have a positive effect on pressure ulcer QMs but CIAs did have a very small positive effect on catheter use QMs. Specifically, pressure ulcer QM scores worsened slightly (0.9 percent) from before the

CIA period to during the CIA period, and then worsened further (0.4 percent) from during the CIA period to after the CIA period ended. By contrast, catheter use QM scores improved slightly (0.3 percent) from before the CIA period to during the CIA period, then improved very slightly again (0.03 percent) from during the CIA period to after the CIA period ended. The results for Ancillary Research Objective One, to determine when any CIA effect occurred relative to the official start date of the CIA, were that varying the starting point of the QM analyses from baseline, when the CIA actually started, to 18 months and then 36 months before the CIA actually started, did not significantly influence when any CIA effect occurred.

The results for Research Objective Two, to assess how certain SNF structural factors and case-mix acuity influenced the effect of quality CIAs on SNF quality of care, were that SNF staffing level and staffing mix both showed the predicted association direction, in that increased staffing levels and improved staffing mix improved pressure ulcer QM scores, but did so at a lower magnitude than expected. By contrast, for catheter use, staffing level and staffing mix showed no association in direction or magnitude that followed my expected pattern which was that increased staffing levels and staffing mix would improve catheter use QMs. Further, Research Objective Two interaction analysis results confirmed statistically significant interaction ($p \leq 0.05$) between staffing level and staffing mix and between staffing level and acuity, but these interactions did not meaningfully impact the study results because the fixed effects coefficients for each of the interaction terms was very small. Research Objective Two results also contradicted my expectation that CIAs would significantly impact staffing levels and staffing mix.

CIAs were not significantly associated with positive changes in staffing level but were associated with small but statistically significant changes in staffing mix.

The results for Research Objective Three, which was to explore the individual effect of each of the 42 CIAs in this study on its SNFs' quality of care, confirmed that CIAs did not well explain either pressure ulcer or catheter use QM variance, and that only a subset of SNF QM data, analyzed at the individual CIA level, demonstrated statistically significant results because of data limitations. Additional results for Research Objective Three, to examine the specific characteristics of those SNFs that showed quality improvement under their CIAs, illustrated that certain SNF characteristics, i.e., occupancy rate, staffing mix, and resident case-mix acuity, appeared to be most associated with CIA responsiveness and SNF quality improvement and were factors that a SNF could adjust during the CIA period to improve its chances of quality improvement during the CIA period.

B. ***Descriptive Statistics and Explanatory Analysis*****.**

1. CIA Trends.

Figures 4-1 and 4-2 illustrate how the number of CIA agreements and the number of CIA-covered SNFs have changed over the course of this study from 2003 to 2015. **Figure 4-1** below shows that a relatively small number of quality CIAs were in effect in 2003; this orange band of active CIAs increased, then remained fairly stable until 2011, when the number of active CIAs began to shrink. By 2012, most of the quality CIAs in my study had ended. The thin orange band starting in 2014 reflects the CIAs for Extendicare Health Services, Inc., and Foundation Health Services, which both started in 2014.

Figure 4-1 - Count of Quality CIAs from 2003 to 2015

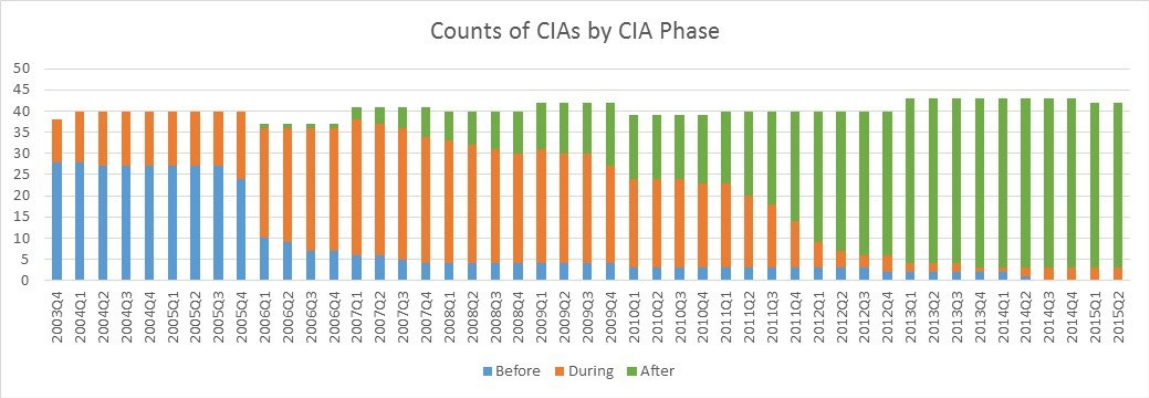
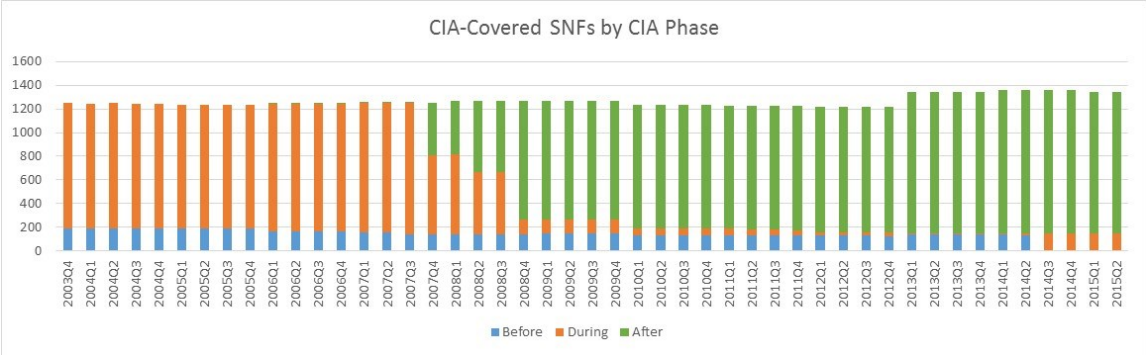


Figure 4-2 below illustrates the fact that CIAs are dramatically different in the number of individual SNFs that they cover. For example, in the time period Q4 2008 to Q4 2011, when **Figure 4-1** above showed the number of active CIAs to be relatively large, **Figure 4-2** reveals that relatively few SNFs were subject to this group of CIAs. Remarkably, from Q4 2012 through Q2 2014 fewer than 10 SNFs were subject to active CIAs. **Table 4-31** below lists the set of 42 CIAs along with their effective dates, number of SNFs covered, and other characteristics.

Figure 4-2 – Count of Quality CIA-Covered SNFs from 2003 to 2015



2. <u>SNF Structural Factors and Acuity.</u>

Table 4-1a and Table 4-1b below show several SNF structural characteristics and the resident case-mix acuity for this study's CIA and non-CIA SNFs <u>by year</u> over the

entire study period. Notably, over this entire study period (as opposed to year-by-year) T-tests based on **Table 4-1a and Table 4-1b** data revealed that CIA SNFs had more residents (CIA SNFs had 2.56 more residents, CI: (-3.03, -2.09), $p<0.001$) and higher occupancy rates (CIA SNFs had a 1.6% higher occupancy rate, CI: (-1.72%, -1.45%), $p< 0.001$) than non-CIA SNFs. An important observation is that CIA SNFs had lower staffing levels than non-CIA SNFs throughout the study period (CIA SNFs used 0.42 fewer staff, CI: (0.41, 0.44), $p<0.001$). Also, the staffing mix (CIA SNFs had a 0.013 higher proportion of RN time, CI: (-0.015, -0.011), $p<0.001$), and the resident case-mix acuity levels (CIA SNFs exhibited only 0.022 higher acuity, CI: (-.027, -.016), $p<0.001$) were relatively similar for both CIA SNFs and non-CIA SNFs during the entire study period. CIA SNFs also appear to have been strongly associated with being part of a SNF corporate chain[83] (35.6% higher proportion of CIA SNFs were part of a chain, CI: (-36.1%, -35.2%), $p<0.001$), and with being for-profit organizations (26.2% higher proportion of CIA SNFs were for-profit entities, CI: (-26.6%, -25.9%), $p<0.001$).

Interestingly, over the course of my study, there were 425 SNFs that converted from not-for-profit to for-profit (17 of those were subject to a CIA) and 203 SNFs that converted from for-profit to not-for-profit (3 of those were subject to a CIA). My statistical models accounted for these changes because the for-profit indicator was a covariate in the model; I also captured the SNF structural factor data annually so as to accurately represent any related changes in QMs.

[83] A SNF was considered to be part of a chain if the same corporate entity operated more than one SNF.

CIA SNFs also tended to be more commonly certified for both Medicare and Medicaid as compared to non-CIA SNFs (3.2% higher proportion of CIA SNFs were dually certified, CI: (3.0%, 3.4%), p<0.001).

Table 4-1a – CIA and non-CIA SNF Structural Characteristics and Acuity by Year, 2003-2009

	2003		2004		2005		2006		2007		2008		2009	
	CIA	No-CIA	CIA	No-CIA	CIA	No-CIA	CIA	No-CIA	CIA	No-CIA	CIA	No-CIA	CIA	No-CIA
Resident Tot.														
Mean	98.7	97.5	97.6	96.7	98.0	96.5	98.7	96.4	98.0	95.0	97.6	94.1	96.9	93.2
SD	39.4	58.2	38.1	58.1	38.4	58.7	39.3	58.5	39.9	57.4	40.0	57.4	39.3	56.7
Obs	1253	10686	4977	43677	4941	44049	4956	44524	5009	45194	5052	46364	5076	46348
Occupancy Rt														
Mean	86.0%	83.7%	85.7%	83.5%	85.9%	83.8%	86.2%	83.9%	85.5%	83.4%	85.1%	83.0%	84.7%	82.2%
SD	12.0%	17.0%	12.4%	16.8%	12.4%	16.3%	12.8%	16.6%	12.9%	16.7%	12.8%	16.6%	12.5%	16.8%
Obs	1253	10686	4977	43677	4941	44049	4956	44524	5009	45194	5052	46364	5076	46348
Staffing Level														
Mean	3.3	3.7	3.3	3.8	3.3	3.8	3.4	3.9	3.4	3.9	3.4	3.9	3.5	4.0
SD	0.9	4.1	0.8	6.0	1.0	5.1	1.0	3.4	1.0	4.3	0.8	4.8	0.8	4.6
Obs	1249	10649	4973	43573	4933	43929	4948	44405	5236	45062	5044	46271	5072	46244
Staffing Mix														
Mean	0.20	0.20	0.20	0.19	0.19	0.20	0.20	0.19	0.19	0.19	0.19	0.19	0.22	0.20
SD	0.26	0.41	0.12	0.29	0.13	0.47	0.14	0.16	0.14	0.24	0.10	0.20	0.57	0.16
Obs	1243	10611	4965	43440	4925	43804	4928	44238	5224	44924	5041	46166	5064	46140
Acuity														
Mean	5.9	5.8	5.9	5.8	5.8	5.8	5.9	5.8	5.9	5.8	5.9	5.8	5.8	5.8
SD	0.6	0.6	0.5	0.6	0.5	0..6	0.5	0.59	0.54	0.6	0.55	0.6	0.54	0.6
Obs	1234	10513	4945	43425	4913	43772	4936	44204	5196	45002	5024	46132	5048	46024
Ind./Chain														
Mean	94%	53%	92%	53%	89%	53%	87%	53%	87%	53%	88%	53,4%	87%	53%
SD	23%	50%	26%	50%	31%	50%	34%	50%	34%	50%	32%	50%	33%	50%
Obs	1253	10686	4977	43677	4941	44049	4956	44524	5009	45194	5052	46364	5076	46348
For Profit/ Non-Profit														
Mean	98%	69%	97%	69%	97%	69%	97%	70%	97%	70%	97%	69%	93%	69%
SD	15%	46%	16%	46%	16%	0..46	17%	46%	17%	46%	17%	46%	25%	46%
Obs	1253	10686	4977	43677	4941	44049	4956	44524	5009	45194	5052	46364	5076	46348
Payer Type														

	2003		2004		2005		2006		2007		2008		2009	
Medicare	1.0%	3.3%	1.0%	3.4%	1.0%	3.4%	0.8%	3.6%	0.8%	3.7%	0.6%	3.9%	0.7%	4.0%
Both	99.0%	96.7%	99.0%	96.6%	99.0%	96.6%	99.2%	96.4%	99.2%	96.3%	99.4%	96.1%	99.3%	96.0%
SD	10.1%	18.0%	10.1%	18.0%	9.8%	18.1%	8.9%	18.6%	8.9%	18.9%	7.9%	19.3%	8.4%	19.5%
Obs	1253	10686	4977	43677	4941	44049	4956	44524	5009	45194	5052	46364	5076	46348

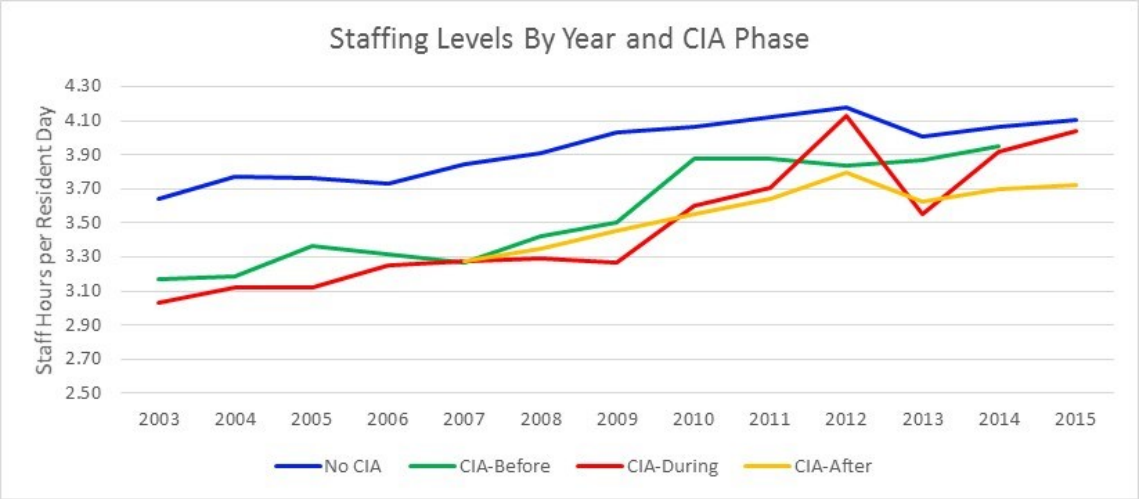
Table 4-1b – CIA and non-CIA SNF Structural Characteristics and Acuity by Year, 2010-2015

	2010		2011		2012		2013		2014		2015	
	CIA	No-CIA	CIA	No-CIA	CIA	No-CIA	CIA	No-CIA	CIA	No-CIA	CIA	No-CIA
Resident Total												
Mean	95.3	92.6	94.7	92.2	93.8	91.3	94.2	91.6	92.6	90.0	91.8	89.5
SD	38.3	56.7	38.5	56.6	39.4	56.2	38.4	56.1	37.8	54.8	37.3	54.9
Obs	4928	46451	4916	46004	4868	46632	5372	49716	5416	52012	2692	26234
Occupancy Rt												
Mean	83.5%	81.9%	83.3%	81.5%	82.3%	81.1%	83.2%	82.9%	82.1%	82.0%	81.3%	81.8%
SD	13.4%	16.8%	13.4%	16.4%	14.1%	16.5%	13.0%	14.8%	13.1%	15.5%	13.4%	15.7%
Obs	4928	46451	4916	46004	4868	46632	5372	49716	5416	52012	2692	26234
Staffing Level												
Mean	3.7	4.1	3.7	4.1	3.8	4.1	3.7	4.0	3.7	4.1	3.8	4.1
SD	1.3	4.2	1.4	4.4	3.7	5.6	0.6	0.9	0.6	0.9	0.7	0.9
Obs	4928	46363	5104	45932	4868	46632	5296	48752	5384	50988	2660	51352
Staffing Mix												
Mean	0.23	0.22	0.25	0.22	0.26	0.23	0.26	0.23	0.26	0.24	0.27	0.25
SD	0.11	0.29	0.12	0.18	0.20	0.28	0.11	0.16	0.14	0.21	0.13	0.20
Obs	4916	46235	5092	45802	4868	46468	5296	48736	5384	50988	2660	51352
Acuity												
Mean	5.9	5.8	5.9	5.8	5.8	5.8	5.9	5.8	5.8	5.8	5.8	5.8
SD	0.57	0.6	0.6	0.6	0.7	0.7	0.5	0.6	0.6	0.6	0.5	0.6
Obs	4920	46179	5056	45712	4868	46632	4860	44964	4768	46608	128	3028
Ind./Chain												
Mean	89%	54%	87%	54%	85%	54%	96%	58%	95%	57%	95%	56%
SD	32%	50%	34%	50%	36%	50%	21%	50%	22%	50%	22%	50%
Obs	4928	46451	4916	46004	4868	46632	5372	49716	5416	52012	2692	26234
For Profit/ Non-Profit												
Mean	93%	70%	94%	70%	95%	70%	98%	70%	97%	71%	95%	71%
SD	26%	46%	23%	.0.46	22%	46%	13%	46%	17%	45%	21%	45%
Obs	4928	46451	4916	46004	4868	46632	5372	49716	5416	52012	2692	26234

	2010		2011		2012		2013		2014		2015	
Payer Type												
Medicare	0.7%	4.1%	0.6%	4.1%	0.6%	4.2%	0.6%	4.2%	0.6%	4.3%	0.7%	4.4%
Both	99.4%	95.9%	99.4%	95.9%	99.4%	95.8%	99.4%	95.8%	99.4%	95.7%	99.3%	95.6%
SD	8.0%	19.8%	7.5%	19.9%	7.6%	20.0%	7.7%	20.0%	7.6%	20.4%	8.2%	20.6%
Obs	4928	46451	4916	46004	4868	46632	5372	49716	5416	52012	2692	26234

Because this study examined SNFs under CIAs over a thirteen-year period where SNFs' CIAs were at different phases across the study period, it is important to examine critical covariate factors such as staffing level by year and by CIA phase. **Figure 4-3** below shows average staffing levels (in hours per resident day (HPRD)) across the study period for CIA and non-CIA SNFs by CIA phase (before, during, or after). As shown in **Table 4-1a and Table 4-1b**, non-CIA SNFs showed a higher overall average staffing level. However, when parsing out the detail of average staffing level per CIA phase, as shown in **Figure 4-3**, it becomes clear that, on average, SNFs did not necessarily increase staffing level in response to CIAs, because the average during-CIA and after-CIA SNF staffing levels are actually lower than the before-CIA staffing levels. **Figure 4-3** also highlights the increased variability of the during-CIA data in 2012 and 2013, most likely because of the small number of CIA-covered SNFs during this period.

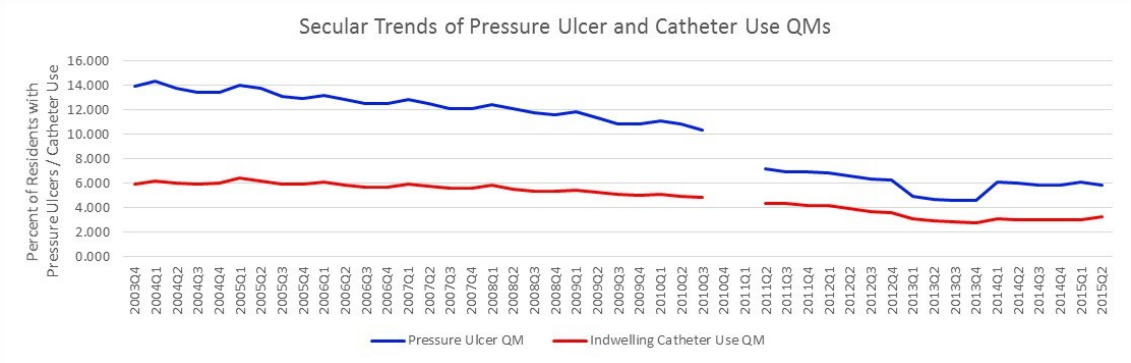
Figure 4-3 Staffing Levels by Year and CIA Phase



3. Quality Measure Explanatory Analysis.

Figure 4-4 below shows the average pressure ulcer and indwelling catheter use QMs reported to CMS over the time period of my study from Q4 2003 to Q2 2015. The secular trend for both pressure ulcers and catheter use is evident from visual inspection – these two overall QM scores were improving. Linear regression confirms that nationally since 2003, pressure ulcer scores have improved 0.2% every quarter and catheter use scores have improved 0.05% every quarter ($p<0.001$). **Figure 4-4** also reveals a QM shift due to the transition from Minimum Data Set (MDS) 2.0 to MDS 3.0 that occurred between Q3 2010 and Q2 2011. This MDS version shift is discussed in greater detail below in **Section C.4 MDS Measure Conversion Analysis Results**; the linear regression model associates on average a 2.0% drop in pressure ulcer quality measures and a 0.9% drop in catheter use QMs with the MDS version change from MDS 2.0 to MDS 3.0 ($p<0.001$).

Figure 4-4 – Secular Trends of Pressure Ulcer and Indwelling Catheter Use QMs Over the Study Period



4. Pressure Ulcer QM Explanatory Analysis.

Figure 4-5 below shows that all SNFs, covered by CIAs or not, showed a consistent secular trend of pressure ulcer QM improvement over the study period, and an improving shift after the reporting gap in 2011-2012 related to the MDS 2.0 to MDS 3.0 change discussed in detail in **Section C.4 of this Chapter**. Interestingly, between 2003 and 2010, both CIA and non-CIA covered SNFs exhibited a wave pattern where Q1 QM scores were higher than Q2, Q3, or Q4 QM scores.[84] This pattern lessened in the later years of the study period.

Figure 4-5 also illustrates marked improvements in pressure ulcer QM scores during the Q1 2013 to Q4 2013 period, but then a return to pre-2013 trends in Q1 2014. Also, with the exception of the 2013 time period, the CIA and non-CIA SNF pressure ulcer QMs appear to be converging; the difference between the two data series gets

[84] I hypothesized that this consistent spike in Q1, known in the industry as the "golden quarter," was related to SNFs taking advantage of increased Medicare Part B funding available in Q1 of each year. Specifically, in January of each year, caps on Medicare Part B funding from the previous year no longer apply and SNFs can begin again to bill for therapy under Medicare Part B. Many SNFs actually send residents with pressure ulcers to therapy (physical and hydro therapy). Therefore, a possible explanation for the annual Q1 spike in pressure ulcer rates is that SNFs increase charting of pressure ulcers in Q1 in order to have more residents qualify for therapy for which the SNFs can bill Medicare Part B and gain additional reimbursement.

narrower over time. While in **Figure 4-5** the CIA SNF QM scores appear to be lower (and therefore better) through 2010, the overall average pressure ulcer QM score is higher (and therefore worse) for CIA SNFs as compared to non-CIA SNFs during this study period (the overall difference between non-CIA SNFs and CIA SNFs was -0.19 percentage points, CI: (-0.26, -0.13) p<0.001).

Figure 4-5- Pressure Ulcer Rates for CIA SNFs and non-CIA SNFs by Quarter

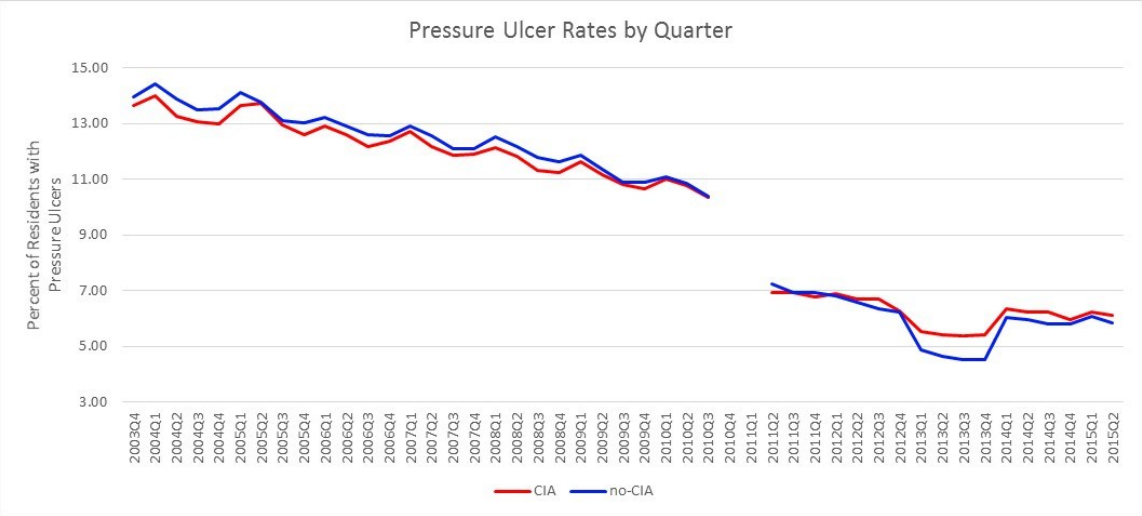


Figure 4-6 below also shows the overall improving pressure ulcer QM trend – and shows that this trend was consistent throughout all of the CMS regions. Notably, Region 2 (New York, New Jersey, Puerto Rico, and the US Virgin Islands) consistently showed the highest (and therefore worst) QM scores. Also, **Figure 4-6** parallels the pronounced year-long 2013 improvement in pressure ulcer scores shown in **Figure 4-5**.

Figure 4-6- Pressure Ulcer Rates for all SNFs by Region and Quarter

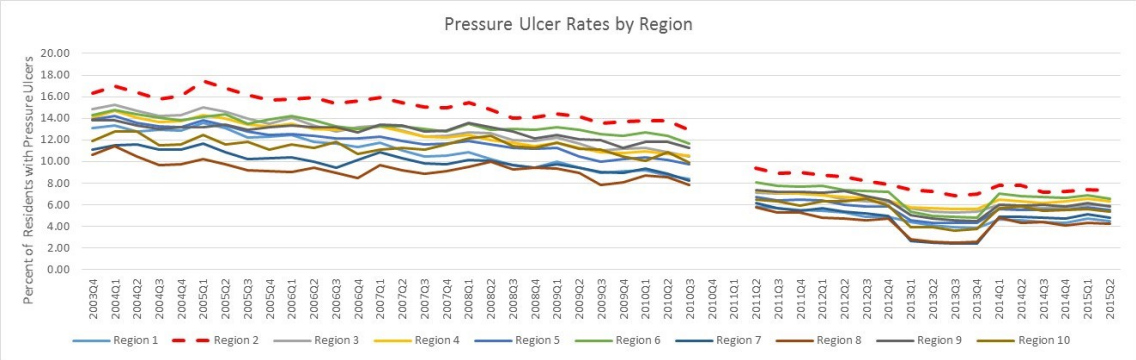


Table 4-2 below shows the average pressure ulcer QM scores for each state for each year in the study. Note that the pressure ulcer improvement trend is broadly consistent for all states. Also note that Puerto Rico and the US Virgin Islands have no reported pressure ulcer QMs; this is because the SNFs in these locations (4 in PR and 1 in VI) most likely have fewer than 30 residents in their pressure ulcer QM denominator and therefore CMS does not report this QM due to low denominator suppression.

Table 4-2 - Pressure Ulcer QMs by State and Year

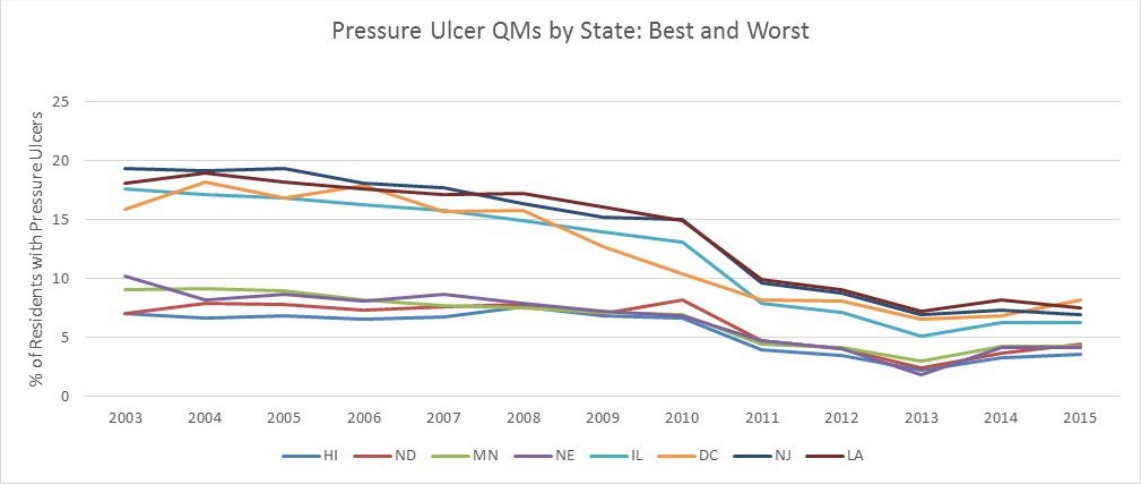
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
AK	13.67	14.17	9.92	6.75	10.00	10.00	12.55	7.13	5.67	7.78	1.94	8.21	5.81
AL	11.37	12.01	12.05	11.90	11.18	10.03	9.08	9.10	6.11	5.74	4.85	5.50	5.71
AR	12.65	13.26	13.10	12.06	11.92	11.44	10.42	10.15	7.17	6.53	5.10	5.55	4.98
AZ	13.10	12.32	10.97	11.42	10.70	11.20	10.10	9.96	6.89	6.38	3.72	5.22	5.37
CA	13.96	13.57	13.43	13.45	13.49	13.27	12.25	11.94	7.31	7.00	4.87	6.07	6.16
CO	11.19	10.65	9.72	8.92	9.29	9.56	9.02	8.71	5.39	4.78	3.12	4.20	4.04
CT	12.61	12.68	12.86	12.03	11.45	10.15	9.36	8.83	5.07	4.66	3.91	4.25	4.47
DC	15.89	18.14	16.83	17.87	15.65	15.80	12.67	10.39	8.22	8.05	6.58	6.82	8.17
DE	15.79	13.97	15.11	12.28	11.84	11.40	9.84	10.05	6.54	5.20	4.73	4.69	4.44
FL	14.43	14.44	14.20	13.65	13.11	12.74	11.97	11.76	6.98	6.47	5.65	6.07	5.91
GA	14.74	15.26	14.93	14.41	13.99	12.20	11.08	10.33	7.19	7.20	6.06	6.64	6.84
HI	7.00	6.61	6.86	6.58	6.77	7.63	6.86	6.60	3.93	3.49	2.25	3.23	3.59
IA	8.31	9.16	8.41	7.51	8.20	8.25	7.96	7.97	4.75	4.25	2.18	4.14	4.06
ID	8.90	8.61	9.16	8.74	8.67	8.89	7.91	7.65	4.77	4.17	2.31	3.33	3.65
IL	17.63	17.12	16.87	16.26	15.75	14.92	13.97	13.04	7.91	7.12	5.10	6.28	6.30
IN	14.45	14.51	13.50	12.25	11.85	11.68	10.32	9.82	6.76	6.16	4.77	5.89	5.98
KS	12.68	12.82	12.03	10.70	10.04	10.14	9.01	9.04	5.39	5.42	2.16	4.75	5.16
KY	15.15	13.71	13.39	13.01	12.27	11.65	10.91	9.95	7.13	6.69	5.77	6.21	6.40

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
LA	18.06	18.92	18.22	17.61	17.14	17.22	16.11	14.95	9.87	9.05	7.22	8.15	7.48
MA	13.69	13.15	12.97	12.21	11.21	10.46	9.57	8.95	6.18	5.57	4.55	4.76	4.96
MD	13.48	14.27	14.11	13.99	13.82	13.51	12.51	12.07	8.00	7.62	6.41	6.92	6.87
ME	10.18	10.17	10.82	8.79	8.92	8.43	8.89	8.59	5.30	5.03	3.19	4.07	4.16
MI	13.01	12.72	12.35	11.78	11.08	10.57	9.46	9.91	6.88	6.23	4.87	5.84	6.17
MN	9.06	9.19	8.99	8.15	7.73	7.51	7.09	6.88	4.45	4.14	2.98	4.19	4.20
MO	12.62	13.54	12.68	12.24	12.12	11.51	11.20	9.99	6.97	6.44	3.22	5.62	5.76
MS	13.90	13.08	13.49	12.96	12.76	12.17	11.50	11.27	7.79	6.96	6.06	7.30	7.50
MT	8.89	8.38	8.49	7.88	8.33	9.78	8.17	7.03	5.20	5.14	1.92	6.05	5.17
NC	14.45	14.61	13.66	12.43	11.84	11.52	11.10	10.73	7.93	7.51	6.52	7.29	7.57
ND	7.03	7.86	7.82	7.35	7.61	7.81	7.04	8.15	4.75	4.01	2.44	3.67	4.39
NE	10.22	8.21	8.63	8.06	8.69	7.93	7.25	6.84	4.70	4.08	1.87	4.16	4.15
NH	13.26	12.10	11.80	10.05	9.27	8.05	7.33	7.43	4.64	4.06	2.97	3.71	3.94
NJ	19.38	19.13	19.35	18.11	17.71	16.37	15.23	14.99	9.64	8.77	6.90	7.30	6.92
NM	11.94	12.08	10.63	11.47	11.07	11.15	9.99	9.61	7.62	6.82	4.27	5.77	6.01
NV	13.63	13.12	14.12	13.70	12.76	12.75	13.18	11.37	7.95	8.29	5.28	7.08	6.27
NY	14.88	14.76	15.10	14.38	14.01	13.58	13.26	12.63	8.78	8.10	7.30	7.60	7.62
OH	14.28	13.70	13.35	12.09	11.74	11.51	10.62	10.03	6.49	6.06	4.37	5.55	5.62
OK	16.16	16.26	15.94	16.84	15.03	15.16	13.78	12.57	8.10	7.95	3.65	7.55	7.56
OR	10.46	12.16	11.67	11.31	11.63	12.32	11.29	9.66	7.01	7.27	3.45	6.55	7.52
PA	14.61	14.07	13.47	12.53	11.86	11.42	10.93	10.41	6.62	5.98	4.89	5.31	5.33
PR													
RI	15.50	16.42	15.18	14.50	11.85	11.61	10.90	9.18	6.21	5.34	4.34	4.82	4.52
SC	13.13	13.29	13.11	12.45	12.37	11.76	11.47	10.84	7.41	6.62	5.20	6.36	6.83
SD	13.58	12.15	10.79	10.72	10.23	10.87	9.00	8.39	6.00	4.85	2.27	5.24	5.14
TN	13.51	13.79	13.22	12.75	12.48	11.82	10.73	10.21	6.64	5.89	4.63	5.36	5.56
TX	13.15	12.60	12.63	12.09	11.76	12.01	12.27	12.01	7.38	7.08	4.78	6.64	6.77
UT	11.40	11.14	9.00	8.88	9.18	9.17	8.79	8.54	6.27	4.58	2.59	4.17	3.93
VA	16.51	16.37	16.46	15.00	14.36	13.58	12.25	11.37	7.51	6.93	5.61	6.26	6.54
VI													
VT	13.38	15.32	13.76	12.32	11.43	9.11	8.44	7.81	5.26	5.10	3.40	4.82	4.52
WA	12.86	12.86	12.29	11.78	11.71	12.28	11.64	11.17	6.36	6.29	4.50	5.76	5.22
WI	11.73	11.21	10.42	10.39	10.08	9.66	9.07	8.62	5.31	4.90	3.32	4.41	4.33
WV	15.16	14.97	14.87	13.60	12.66	13.01	12.12	11.00	7.72	7.52	6.29	6.21	6.78
WY	11.44	11.77	12.69	11.02	11.51	11.91	7.58	7.96	5.78	5.60	2.51	4.06	3.83
Avg	13.10	13.07	12.66	11.95	11.61	11.34	10.49	9.87	6.59	6.13	4.21	5.60	5.61

Figure 4-7 below shows the four states with the highest (worst) pressure ulcer QM scores and the four states with the lowest (best) pressure ulcer QM scores. Hawaii,

North Dakota, Minnesota, and Nebraska show the best pressure ulcer QM scores over the study period, while Illinois, the District of Columbia, New Jersey, and Louisiana show the worst QM scores.

Figure 4-7 - Pressure Ulcer Rates by State and Year: the 4 Best and the 4 Worst



5. Catheter Use QM Explanatory Analysis.

Figure 4-8 below shows that all SNFs, covered by CIAs or not, showed catheter use QM improvement over the study period, and a positive (improving) shift after the reporting gap in 2011-2012, related to the MDS 2.0 to MDS 3.0 shift (very similar to the pressure ulcer trends shown in **Figure 4-5** above). Again, for catheter use QMs, both CIA and non-CIA covered SNFs exhibited the annual wave pattern, which seemed to dissipate in the later study years, as did the pressure ulcer QM pattern. **Figure 4-8** below reveals marked improvements in catheter use QM scores during 2013, but then shows a return to pre-2013 trends in 2014. Also, with the exception of the 2011-2013 time period, the CIA and non-CIA SNF catheter use QMs appear to be converging; the difference between the two data series gets narrower over time. Similar to the pressure ulcer QMs, the overall average catheter use QM scores were higher (and therefore worse) for CIA

SNFs as compared to non-CIA SNFs (the difference between CIA SNFs and non-CIA SNFs was -0.25 percentage points, CI: (-0.28, -0.21) p<0.001).

Figure 4-8- Catheter Use Rates for CIA SNFs and non-CIA SNFs by Quarter

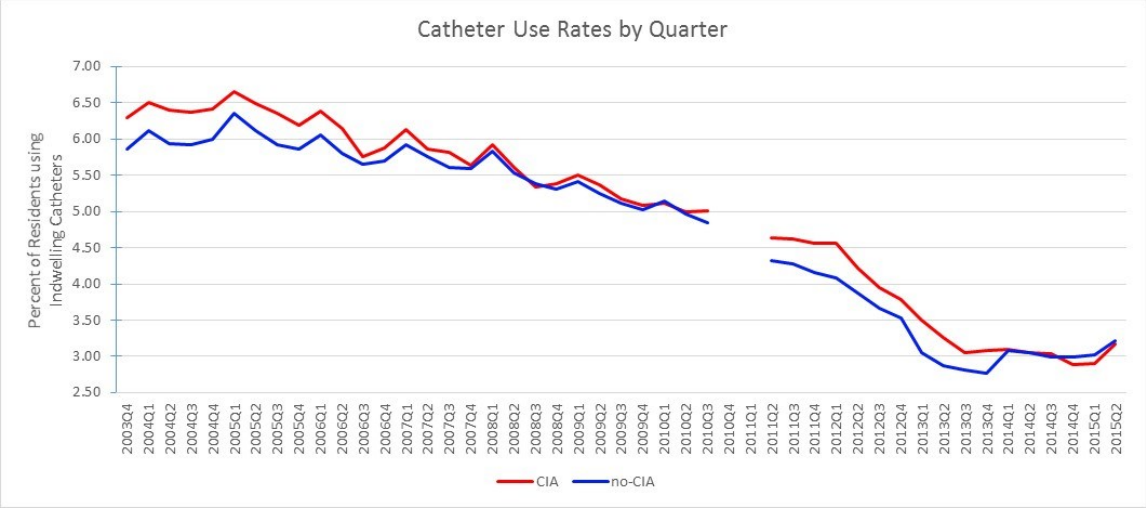


Figure 4-9 below also shows the overall catheter use QM improving trend – and shows that this trend was reasonably consistent throughout all of the CMS regions. Region 10 (Washington, Oregon, and Idaho) shows the highest (and therefore worst) QM scores. It is interesting to note that while Region 2 was the worst CMS region for pressure ulcer QMs, Region 2 was among the best regions for catheter use QMs. Also interesting is the fact that, while Region 10 was the worst region for catheter use QMs, it was among the best regions for pressure ulcer QMs. **Figure 4-9** also illustrates the pronounced year-long 2013 improvement in catheter use rates which was seen in **Figure 4-8**.

Figure 4-9- Catheter Use Rates for all SNFs by Region and Quarter

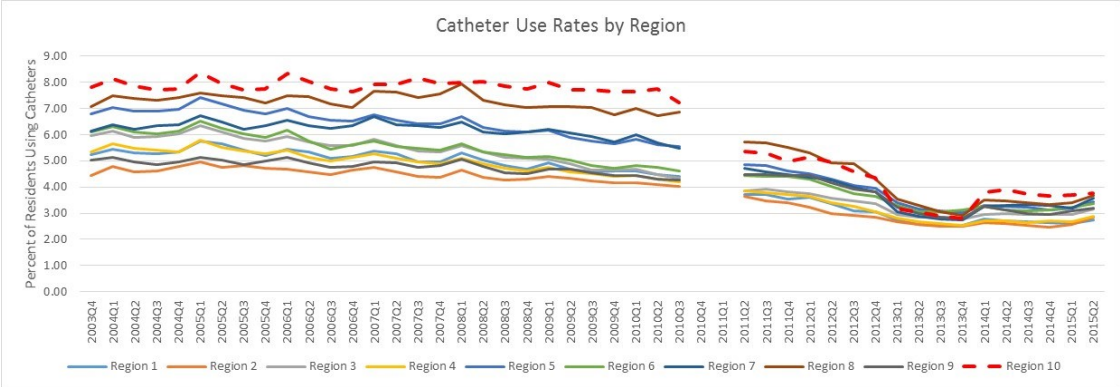


Table 4-3 below shows the average catheter use QM scores for each state for each year in the study. As with pressure ulcer QM scores by state, note that the catheter use improvement trend is consistent for all states, and that Puerto Rico and the US Virgin Islands have no reported catheter use QMs, likely because of CMS' low denominator suppression.

Table 4-3 – Catheter Use QMs by State and Year

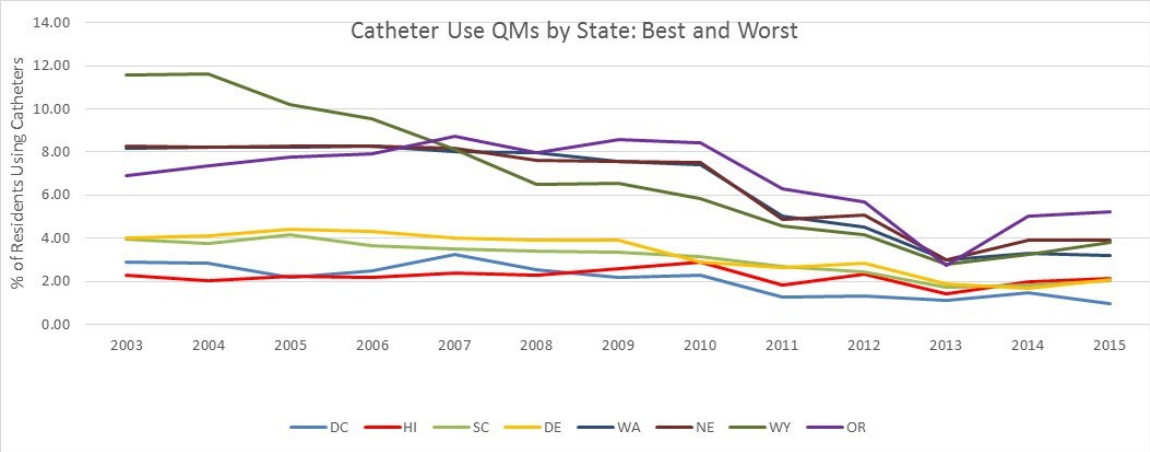
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
AK	11.33	12.11	10.22	8.00	9.75	8.00	9.33	8.89	8.14	6.72	4.22	7.17	5.53
AL	4.77	4.74	4.97	4.62	4.53	4.24	4.09	3.87	3.67	3.32	2.75	2.65	2.84
AR	6.04	6.11	6.19	5.58	5.73	5.31	4.83	4.35	4.12	3.90	3.27	3.04	3.04
AZ	6.70	6.37	6.61	6.12	6.25	6.16	6.14	5.81	5.13	4.90	3.03	3.47	3.03
CA	4.86	4.83	4.87	4.78	4.70	4.55	4.36	4.13	4.33	3.98	2.95	3.02	3.14
CO	6.81	7.27	7.38	7.21	7.49	7.43	6.92	6.88	6.36	5.11	3.39	3.20	3.16
CT	4.55	4.66	4.90	4.70	4.42	4.23	3.97	3.71	3.01	2.80	2.38	2.28	2.16
DC	2.92	2.85	2.16	2.51	3.23	2.55	2.17	2.28	1.29	1.33	1.14	1.49	0.96
DE	4.03	4.11	4.40	4.31	4.01	3.94	3.93	2.92	2.65	2.86	1.87	1.66	2.09
FL	5.81	5.97	6.03	5.73	5.63	5.43	4.99	4.76	3.82	3.37	2.71	2.74	2.81
GA	4.39	4.21	4.11	4.00	4.01	3.87	3.72	3.38	2.65	2.65	2.04	2.09	2.22
HI	2.27	2.04	2.22	2.19	2.37	2.30	2.59	2.89	1.85	2.35	1.44	1.96	2.14
IA	5.81	6.20	6.67	6.65	6.81	6.72	6.64	6.11	5.31	4.63	3.35	3.94	4.18
ID	7.98	6.84	6.83	6.56	6.30	7.50	6.97	6.70	4.42	4.01	3.19	3.28	2.98
IL	6.70	6.81	6.96	6.66	6.25	6.09	5.51	5.40	4.97	4.55	3.52	3.59	3.83
IN	7.36	7.47	7.50	6.98	6.91	6.53	5.91	5.48	4.75	4.09	3.08	2.85	2.84
KS	6.05	6.28	6.21	5.87	5.91	5.94	5.65	5.43	4.16	3.61	2.32	2.85	2.87
KY	6.64	7.02	6.94	6.50	6.29	5.96	6.05	5.63	5.50	4.70	3.65	3.34	3.64

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
LA	7.64	7.80	7.88	7.31	7.06	6.79	5.71	5.22	4.45	3.88	2.95	2.72	2.74
MA	5.23	5.05	5.17	4.99	4.87	4.75	4.53	4.36	3.66	3.07	2.40	2.57	2.68
MD	3.96	4.18	4.50	4.16	4.08	3.97	3.56	3.50	3.20	2.89	2.39	2.39	2.55
ME	6.46	6.65	6.60	6.54	6.92	6.17	6.04	5.59	3.97	4.34	3.10	3.64	3.46
MI	5.77	5.68	5.59	5.65	5.43	5.21	4.80	4.79	4.32	3.87	3.05	3.22	3.44
MN	5.87	6.13	6.23	6.15	6.29	6.17	6.13	5.96	4.46	4.25	2.98	3.07	3.13
MO	5.66	5.77	5.61	5.68	5.76	5.34	5.00	4.92	4.14	3.62	2.71	2.83	2.87
MS	4.99	5.42	5.24	4.85	4.91	4.42	4.05	3.61	3.52	3.07	2.48	2.36	2.65
MT	5.95	6.08	6.09	7.15	7.59	6.79	6.53	6.44	5.57	5.65	3.29	3.80	3.92
NC	4.75	4.79	4.76	4.60	4.36	4.37	4.20	4.01	3.61	3.21	2.58	2.78	2.71
ND	6.74	7.37	8.00	7.59	8.31	8.08	7.37	7.35	5.05	4.47	2.87	3.25	3.15
NE	8.29	8.23	8.30	8.26	8.18	7.62	7.54	7.53	4.89	5.08	2.98	3.92	3.90
NH	5.24	6.06	6.85	6.69	6.67	6.35	6.25	6.23	4.85	4.62	3.74	3.98	3.89
NJ	4.80	5.00	5.28	4.92	4.69	4.41	4.23	4.13	3.61	3.04	2.51	2.57	2.77
NM	5.82	5.94	5.45	5.78	5.26	5.15	4.62	4.62	4.37	3.65	3.07	3.03	3.32
NV	5.70	6.08	6.35	5.84	6.26	6.22	6.95	6.41	6.63	6.40	4.14	4.63	4.41
NY	4.27	4.50	4.55	4.42	4.42	4.37	4.32	4.08	3.44	2.97	2.60	2.56	2.68
OH	7.41	7.60	7.84	7.09	6.97	6.65	6.21	5.93	4.78	3.92	2.96	3.08	2.98
OK	6.69	6.92	7.24	6.68	6.64	6.20	5.56	5.24	5.03	4.51	3.50	3.78	4.03
OR	6.88	7.36	7.78	7.94	8.72	7.97	8.58	8.40	6.28	5.70	2.75	5.04	5.25
PA	6.51	6.66	6.58	6.34	6.19	5.86	5.30	4.98	4.24	3.88	3.11	3.32	3.37
PR													
RI	5.05	5.43	5.02	4.86	4.28	4.58	4.16	3.98	3.45	2.85	2.23	2.16	2.12
SC	3.95	3.75	4.15	3.66	3.49	3.42	3.34	3.16	2.70	2.46	1.71	1.82	2.03
SD	7.52	7.45	7.27	7.13	7.79	7.46	7.27	7.34	5.38	5.00	3.72	4.18	4.64
TN	6.31	6.52	6.64	6.05	5.91	5.51	5.20	4.63	4.32	3.74	3.00	3.19	3.13
TX	5.52	5.47	5.42	5.07	4.81	4.76	4.62	4.56	4.34	3.85	3.00	3.13	3.29
UT	6.86	7.06	7.01	6.73	6.30	7.04	6.95	6.33	5.75	3.64	2.60	3.03	3.13
VA	5.40	5.35	5.46	5.11	4.79	4.60	4.26	4.09	3.55	3.20	2.57	2.65	2.64
VI													
VT	7.37	8.18	9.29	7.73	7.76	7.77	7.16	7.00	4.82	4.87	3.28	3.56	3.16
WA	8.16	8.22	8.24	8.25	8.03	7.97	7.55	7.41	5.04	4.52	3.02	3.30	3.21
WI	6.83	7.21	7.34	7.01	6.92	6.89	6.57	6.62	5.05	4.63	3.46	3.58	3.81
WV	8.67	7.88	7.88	7.23	6.82	6.68	6.04	5.41	4.73	4.24	3.65	3.34	3.71
WY	11.58	11.64	10.20	9.56	8.13	6.51	6.53	5.86	4.59	4.15	2.78	3.25	3.83
Avg	6.13	6.26	6.29	6.00	5.98	5.74	5.51	5.26	4.39	3.96	2.84	3.08	3.12

Figure 4-10 below shows the four states with the highest (worst) catheter use QM scores and the four states with the lowest (best) catheter use QM scores. The District of

Columbia, Hawaii, South Carolina, and Delaware show the best catheter use scores over the study period, while Washington State, Nebraska, Wyoming and Oregon show the worst scores. The state-level analysis reinforces the CMS Region-level analysis in that Washington and Oregon, two of the four worst catheter use QM states, are both part of CMS Region 10, the worst-performing CMS Region according to catheter use QMs.

Figure 4-10 - Catheter Use Rates by State and Year: the 4 Best and the 4 Worst



C. *Research Objective One: Main Findings related to Whether Quality CIAs had a Positive Effect on SNF Quality of Care as Measured by Pressure Ulcer and Catheter Use QMs.*

My hypotheses for Research Objective One, related to the question of whether quality CIAs had a positive effect on SNF quality of care over and above any unrelated national SNF quality of care trends, were that a SNF would improve both pressure ulcer and catheter use QM scores some time before entering and during the pendency of its quality CIA, but that the SNF's QM scores would worsen at some point after the CIA period expired.

My study results were that CIAs do not have a positive effect on pressure ulcer QMs, but do have a very small positive effect on catheter use QMs. A further finding

was that the correlation of QM scores within SNFs was significant. Conversely, the correlation of QM scores within CIAs was not significant.

1. Pressure Ulcer QM Results.

Table 4-4 below[85] shows the fixed effects results from the Research Objective One mixed effects regression model analysis for pressure ulcers. As expected from the explanatory analyses, the regression model showed that pressure ulcer QM scores improved (decreased) over time (-0.18% per time period (quarter), CI: (-0.180, -0.176), $p< 0.001$). The results also showed that MDS 2.0 scores were higher (and therefore worse) than MDS 3.0 scores (1.71% higher, CI: (1.659, 1.769), $p<0.001$). **Table 4-4** also shows that pressure ulcer QM scores for SNFs transitioning into CIAs (from before to during CIAs) were higher (and therefore worsened) (0.90 higher, CI: (0.586, 1.218), $p<0.001$), and that QM scores worsened even more (1.30 higher, CI: (0.976, 1.630), $p< 0.001$) when SNFs transitioned out of CIAs (from before to after CIAs). This result is contrary to my hypothesis that the before-to-during CIA phase transition would be positively associated with SNF quality as defined, in part, by pressure ulcer QM improvement. A possible explanation for this result is that the *accuracy* of pressure ulcer measurement could have improved during the CIA under CIA quality monitoring, which in turn could have uncovered higher rates of pressure ulcers in SNFs than were reported before the SNFs entered the CIAs.

[85] The coefficient for the transition from during-to-after a CIA, "CIA_PHASE 1-2" in **Table 4-4**, was calculated as the difference between the before-to-during and the before-to-after transition coefficients. The standard error, p-value, and confidence interval were not determined for "CIA_PHASE 1-2."

Table 4-4- Pressure Ulcer Fixed Effects Regression Results for Research Objective One

	Coefficient	Standard Error	P>z	[95% Confidence Interval]	
TIME_PERIOD	-0.18	0.00	0.000	-0.180	-0.176
MDS2	1.71	0.03	0.000	1.659	1.769
CIA_PHASE 0-1	0.90	0.16	0.000	0.586	1.218
CIA_PHASE 0-2	1.30	0.17	0.000	0.976	1.630
CIA_PHASE 1-2	0.40				
CONSTANT	13.10	0.34	0.000	12.426	13.774

Table 4-5 below shows the random effects (at the CIA and SNF/provider number levels) results from the Research Objective One mixed effects regression model analysis for pressure ulcers. The variance of the CIA errors (shown as γ_j in the model in **Chapter 3 Methods**) was 1.34, while the variance of the SNF/provider number errors (shown as υ_i in the model) was 12.73. The residual error variance (shown as ε_{ijt} in the model) was 24.16. **Table 4-5** also shows the correlation between QM scores for a given CIA and between QM scores for a given SNF. Correlation, calculated as the variance of each grouping variable divided by the sum of the grouping variable variances plus the residual variance, shows that SNF pressure ulcer QM scores are very much correlated by provider number over time (33.3%), while pressure ulcer QM scores are essentially not correlated within CIAs (3.5%).

Table 4-5- Pressure Ulcer Random Effects Regression Results for Research Objective One

	Estimate	Standard Error	[95% Confidence Interval]		Correlation
CIA variance	1.335	0.716	0.466	3.822	3.5%
PROVNUMBER variance	12.728	0.168	12.403	13.061	33.3%
RESIDUAL variance	24.160	0.052	24.058	24.263	

2. Catheter Use QM Results.

Table 4-6 below shows the fixed effects results from the Research Objective One mixed effects regression model analysis for catheter use. As expected from the explanatory analyses, the regression model showed that catheter use QM scores improved (decreased) over time (-0.06% per time period (quarter), CI: (-0.058, -0.056), $p< 0.001$). The results also showed that MDS 2.0 scores were higher (and therefore worse) than MDS 3.0 scores (0.89% higher, CI: (0.866, 0.921), $p<0.001$).

Table 4-6 also shows that catheter use QM scores for SNFs transitioning into CIAs (from before to during CIAs) improved slightly (0.34 lower, CI: (-0.504, -0.178), $p<0.001$), and that catheter use QM scores similarly improved slightly (0.31 lower, CI: (-0.483, -0.145), $p< 0.001$) when SNFs transitioned out of CIAs (from before to after CIAs). The catheter use fixed effects coefficients represented a slight increase (0.03) in (and therefore worsening of) QM scores when comparing during-CIA to after-CIA phase. These results supported my hypothesis that CIAs would be positively associated with SNF quality improvement as measured by rate of indwelling catheter use but that after the CIA term ended, SNF quality of care would worsen. While these results supported by hypotheses in direction, they did not support my hypotheses in magnitude given that the catheter use QM improvement was so slight.

These results may be explained by improved clinical process changes and increased quality monitoring under the CIA, which influenced clinical processes to reduce indwelling catheter use whenever catheters were not medically indicated. Compared to the CIA association with worsening pressure ulcer QMs where I suggested

possible detection bias, here there is no subjectivity in determining whether a SNF resident is using an indwelling catheter.

Table 4-6- Catheter Use Fixed Effects Regression Results for Research Objective One

	Coefficient	Standard Error	P>z	[95% Confidence Interval]	
TIME_PERIOD	-0.06	0.00	0.000	-0.058	-0.056
MDS2	0.89	0.01	0.000	0.866	0.921
CIA_PHASE 0-1	-0.34	0.08	0.000	-0.504	-0.178
CIA_PHASE 0-2	-0.31	0.09	0.000	-0.483	-0.145
CIA_PHASE 1-2	0.03				
CONSTANT	5.92	0.18	0.000	5.566	6.275

Table 4-7 below[86] shows the random effects (at the CIA and SNF/provider number levels) results from the Research Objective One mixed effects regression model analysis for catheter use QMs. The variance of the CIA errors (shown as γ_j in the model) was 0.31, while the variance of the SNF errors (shown as υ_i in the model) was 5.13. The residual error variance (shown as ε_{ijt} in the model) was 7.38. **Table 4-7** also shows the correlation between QM scores for a given CIA and between QM scores for a given SNF. The correlation shows that SNF catheter use QM scores were very much correlated by provider number over time (41.0%), while catheter use QM scores were essentially not correlated within CIAs (4.0%). These catheter use correlation results were analogous to the correlations found for pressure ulcers.

[86] Note that **Table 4-7** does not show standard errors and confidence intervals for the CIA and SNF/provider number variances. This is because the Stata mixed command could not converge on a solution during the gradient-based maximization stage of estimation. I therefore restricted processing on this model to the expectation-maximization iteration method, which cannot generate standard errors. Using this approach does not impact the fixed effects results because the expectation-maximization (not the gradient-based maximization) is used for the fixed effects results.

Table 4-7- Catheter Use Random Effects Regression Results for Research Objective One

	Estimate	Standard Error		[95% Confidence Interval]	Correlation
CIA variance	0.306				4.0%
PROVNUMBER variance	5.133				41.0%
RESIDUAL variance	7.383				

3. Discussion of the "CIA 0" Approach and How it is Supported by the Results.

For this study, I associated each CIA-covered SNF with a sequence number uniquely identifying the CIA to which the SNF(s) was subject. I associated non-CIA covered SNFs with a fictional CIA "CIA 0" and I also associated non-CIA SNFs with the Phase 0 ("before") for all time periods in the study. The advantage of this approach was that I was able to include the entire SNF population in the Research Objective One analysis and thereby identify national SNF QM trends. A potential concern with this approach was that the national SNF population could bias the CIA SNF analysis by overwhelming the CIA SNF QMs in the before CIA phase with non-CIA QMs and potentially diluting or concealing CIA effects on SNF QM results. This concern was allayed after comparing the results of Research Objective One with the results of Research Objective Three (a CIA-only SNF analysis) which showed that my data set functions in such a way that the national SNF population did not bias the CIA SNF analysis. Specifically, a comparison of the mixed effects linear regression analysis results from Research Objective One (where the entire SNF population is included, with "CIA 0" SNFs) and from Research Objective Three (where only CIA SNFs are included, without "CIA 0" SNFs) makes it clear that CIA effects in my dataset are not concealed by the national non-CIA SNFs. **Table 4-17** below in **Section F** shows the coefficients from each model (all SNFs versus CIA SNFs) for pressure ulcers, and all of the coefficient

results from the model (time period, MDS2, CIA Phase 0-1, and CIA Phase 0-2) were consistent in magnitude and direction for Research Objective One and for Research Objective Three. Therefore, whether I included all SNFs in the model as "CIA 0" or just CIA SNFs in the model made little difference in evaluating the effect of CIAs on QMs. In sum, the "CIA 0" approach was determined to be reasonable and valid.[87]

4. MDS Measure Conversion Analysis Results.

As discussed in the **Chapter 3 Methods** section, the two alternatives for addressing the instrumentation change from MDS 2.0 to MDS 3.0 that I considered were: (1) including an MDS version indicator in the statistical models, or (2) "standardizing" scores across the MDS version change by adjusting one set of the raw QM scores to match the other set. In the final analysis, I selected the first approach to include an MDS version indicator in the statistical models.

I also explored the alternative adjustment approach to ascertain whether that approach would yield similar results. To implement this alternative, I: (1) computed the national average for the two MDS 2.0 QM scores and national average for the two MDS 3.0 QM scores; (2) calculated an adjustment ratio for each QM by comparing the MDS 2.0 national average for that QM to the MDS 3.0 national average for that QM; and then (3) multiplied the MDS 3.0 QM scores by the adjustment ratio in (2) above to align the MDS 3.0 with the MDS 2.0 values. This approach is summarized in **Table 4-8.**

[87] I considered an alternative approach to "CIA 0" to create a fourth value in the categorical variable CIA Phase for those non-CIA SNFs that I placed under "CIA 0". However, as discussed, the simpler, three-phase approach to group the non-CIA SNFs together with the CIA SNFs in the 'before' phase had little impact on the mixed effects regression analyses results. Further, I determined that creating a fourth value was inappropriate because it was important to have both the CIA SNFs and the non-CIA SNFs *together* in the "before" CIA phase category to accurately characterize the transition of a SNF into a CIA. Before a SNF becomes subject to a CIA, it technically is part of the non-CIA population, and therefore the model I selected for Research Objective One is a more accurate representation.

Table 4-8 - Quality Measures Adjusted for MDS 2.0 versus MDS 3.0

Descriptor	MDS 2.0 Code	Average	Adj.	MDS 3.0 Code	Average	Maps to	Adj.
Pressure Ulcers QMs	303	11.859	1.000	403	5.662	303	2.094
Indwelling Catheter Use QMs	306	5.527	1.000	406	3.212	306	1.721

To examine any differences in outcomes when using the regression model MDS conversion versus the adjustment factor MDS conversion, I ran the Research Question One model using both conversion methods and graphed the fixed portion of the mixed effects regression results as shown below in **Figure 4-11** and **Figure 4-12**. **Figure 4-11** shows that compared to including an MDS factor in the statistical model, adjusting the pressure ulcer MDS 3.0 QM scores "up" to align with the MDS 2.0 scores would have a very small effect on the slope of the relationship between QM scores and CIA Phase.

Figure 4-11 – Comparison of including MDS in the Model vs Adjusting Pressure Ulcer QMs

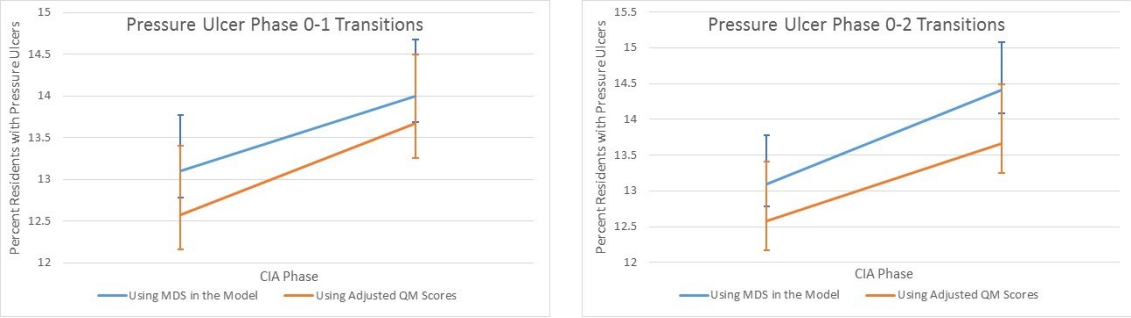
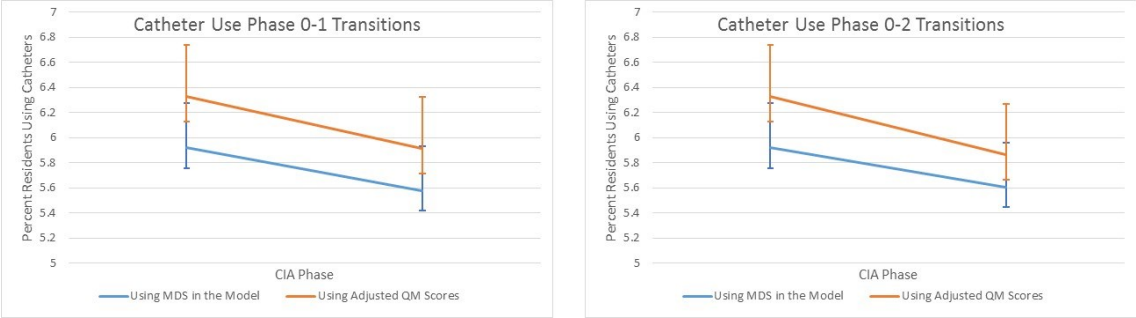


Figure 4-12 shows similar results for catheter use QMs. For both pressure ulcers and catheter use, and for both the CIA before-to-during phase transition and the before-to-after phase transition, the direction and magnitude of the slopes of the statistical model and the adjustment approach were quite similar (the slope of the blue lines (using MDS in the model) is similar to the slope of the orange lines (using adjusted QM scores)). I determined that it was preferable to include the MDS version indicator in the statistical model (either MDS 2.0 or 3.0) and use raw, unadjusted QMs in the graphics and in the

analyses because this approach provided better fidelity to the data over time, and avoided using a constant adjustment factor.

Figure 4-12 – Comparison of including MDS in the Model vs Adjusting Catheter Use QMs



5. Ancillary Research Objective One Results.

My hypotheses for Ancillary Research Objective One, which addressed *when* any CIA effect may have occurred relative to the official start of the CIA, were that the fixed effects coefficients would reflect greater improvement for chain SNFs than single facility SNFs when the start of the CIA was shifted to 18 to 36 months earlier than the official CIA start date. This is because I predicted that corporate SNF chains, which typically begin negotiations with the federal government on health care fraud cases years before a CIA is imposed would begin to improve quality QMs years before the official CIA start date because they would realize they were under significant regulatory scrutiny. By contrast, I hypothesized that CIAs would have the most improvement impact on single facility SNFs in the baseline case, meaning that single facility SNFs would only begin to show QM improvement at the official start of the CIA because government investigations into single facility SNFs are often much more expedited.

The study results showed that for chain SNFs, the CIA effect was stronger (there was a more negative association with QMs) when the CIA start date was shifted to 18 and

to 36 months before the official CIA start date. The results further showed that the CIA effect for single SNFs was inconsistent across CIA phases. The limitations of this analysis could have been that a large number of CIA-covered SNFs (over 1,100 of the 1,400 in this study) were already under active CIAs at the start of this study period in 2003, so moving back the CIA start date had no measurable effect on a large portion of the CIA-covered SNFs. Further, an effect of shifting the CIA start to an artificially earlier time period meant that more "before" QM scores were converted into "during" QM scores. This CIA shift could have exacerbated the existing data gaps in actually available "before" QM values, particularly in single-facility SNFs, as evidenced by the non-significant p-values in many of the single SNF results shown in **Table 4-9** below, where several p-values for the CIA Phase coefficients were greater than 0.05. (See also **Table 4-31** in **Section G.3** addressing CIA Phase Data Gaps).

Table 4-9 presents results from this CIA phase offset analysis for pressure ulcer QMs and shows that the CIA worsening effect for chain SNF pressure ulcer QMs did indeed get smaller with a greater CIA start period offset, e.g., the before-during transition coefficient dropped from 1.02 ($p<0.001$) to 0.060 ($p<0.001$) with an 18 month earlier CIA start, and then dropped again to 0.04 ($p<0.001$) with a 36 month earlier CIA start. **Table 4-9** also shows that the CIA worsening effect for single SNF pressure ulcer QMs was inconsistent in that the before-to-during "PHASE 0-1" change got worse with a longer CIA start offset, but the before-to-after "PHASE 0-2" change started to improve with a longer CIA start offset. These pressure ulcer Ancillary Research Objective One results do not clearly support the hypothesis that when compared to single-facility SNFs,

chain SNFs are more likely to reflect a change in quality outcome earlier than the official start date of a CIA.

Table 4-9- Pressure Ulcer Fixed Effects Coefficients, with CIA Impact and CIA Phase Offsets

	Coefficient	Baseline	P-value	18 Month Offset	P-value	36 Month Offset	P-value
Single SNFs	Time	-0.17	p<0.001	-0.17	p<0.001	-0.17	p<0.001
	MDS2	1.76	p<0.001	1.76	p<0.001	1.76	p<0.001
	PHASE 0-1	0.84	0.080	1.14	0.019	0.67	0.226
	PHASE 0-2	0.68	0.171	0.97	0.052	0.52	0.358
CHAIN SNFs	Time	-0.18	p<0.001	-0.18	p<0.001	-0.18	p<0.001
	MDS2	1.67	p<0.001	1.67	p<0.001	1.67	p<0.001
	PHASE 0-1	1.02	p<0.001	0.60	p<0.001	0.04	0.771
	PHASE 0-2	1.50	p<0.001	1.09	p<0.001	0.54	p<0.001

Table 4-10 below presents results from this CIA phase offset analysis for catheter use QMs and shows that the CIA improvement effect for chain SNF catheter use QMs did indeed get better with a greater CIA start period offset, e.g., the before-to-during transition coefficient dropped from -0.45 (p<0.001) to -0.89 (p<0.001) with an 18 month earlier CIA start, and then remained flat at -0.88 (p<0.001) with a 36 month earlier CIA start. **Table 4-10** shows that the CIA improvement effect for single SNF catheter use QMs was inconsistent: the before-to-during "PHASE 0-1" change got worse with a longer CIA start offset, but the before-to-after "PHASE 0-2" change did start to improve with a longer CIA start offset. These catheter use Ancillary Research Objective One results do not clearly show that, compared to single-facility SNFs, chain SNFs are more likely to reflect a change in quality outcome sooner relative to the official start of a CIA.

Therefore, my conclusion from Ancillary Research Objective One is that my original hypothesis that SNF chains would see quality improvements 18 to 36 months before their actual CIA start dates was not supported.

Table 4-10- Catheter Use Fixed Effects Coefficients with CIA Impact and CIA Phase Offsets

	Variable	Baseline	P-value	18 Month Offset	P-value	36 Month Offset	P-value
Single SNFs	Time	-0.05	p<0.001	-0.05	p<0.001	-0.05	p<0.001
	MDS2	0.87	p<0.001	0.87	p<0.001	0.87	p<0.001
	PHASE 0-1	0.33	0.011	0.17	0.191	0.11	0.440
	PHASE 0-2	0.42	0.002	0.29	0.034	0.23	0.099
CHAIN SNFs	Time	-0.06	p<0.001	-0.06	p<0.001	-0.06	p<0.001
	MDS2	0.90	p<0.001	0.89	p<0.001	0.89	p<0.001
	PHASE 0-1	-0.45	p<0.001	-0.89	p<0.001	-0.88	p<0.001
	PHASE 0-2	-0.34	p<0.001	-0.78	p<0.001	-0.78	p<0.001

D. *Research Objective Two Results Reporting: Main Findings Related to How Certain SNF Characteristics Influence the Effect of CIAs on SNF Quality of Care.*

My Research Objective Two hypothesis was that certain key SNF characteristics, including staffing level, staffing mix, payer type, for-profit status, occupancy rate, and resident case-mix acuity, among others, could serve as significant predictors of pressure ulcer and catheter use QM outputs. Specifically, I expected that an increase in staffing level and an improved staffing mix, in particular, would be strongly associated with an improvement in these two QMs. The results for Research Objective Two generally illustrated that while staffing levels and staffing mix did show some association with QM improvement, staffing levels and staffing mix did not show the consistently significant association with QM improvement that I had predicted.

1. SNF Structural Factors and Acuity.

Table 4-11 below lists the fixed effects outputs from the mixed effects linear regression analyses that included SNF structural factors and resident case-mix acuity in the model. The first key observation is that the coefficients for the time variable (in quarters) and the MDS variable did not change from the crude Research Objective One

regression model discussed in **Section C** above. However, the introduction of the numerous other SNF characteristic covariates into the model had a diluting effect and reduced the magnitude of the coefficients for the CIA phase variables. Specifically, the coefficients reported in Research Objective Two moved from 0.9 (in Research Objective One) to 0.72 (in Research Objective Two) for pressure ulcer QMs in the before-to-during phase transition. For catheter use, the coefficient for the CIA phase moved from -0.34 (in Research Objective One) to -0.13 (in Research Objective Two) for catheter use QMs in the before-to-during phase transition. This dilution could signal a confounding effect between CIA phase and other covariates, as discussed in **Section D.3** below.

Another impact of adding all of the Research Objective Two covariates was that the significance of the catheter use CIA phase transitions changed from significant to *not significant* (p=0.143) for the before-during CIA phase transition. A detailed discussion of the results on each of the study covariates for pressure ulcer and catheter use QMs follows **Table 4-11** below.

Table 4-11- Fixed Effects Regression Results for Research Objective Two

	Pressure Ulcer					Catheter Use				
	Coef.	Std. Err.	P>z	[95% Conf. Interval]		Coef.	Std. Err.	P>z	[95% Conf. Interval]	
TIME_PERIOD	-0.18	0.00	0.000	-0.187	-0.183	-0.06	0.00	0.000	-0.059	-0.057
MDS2	1.70	0.03	0.000	1.645	1.758	0.88	0.01	0.000	0.851	0.906
CIA PHASE 0-1	0.72	0.19	0.000	0.349	1.087	-0.13	0.09	0.143	-0.312	0.045
CIA PHASE 0-2	1.20	0.19	0.000	0.818	1.575	-0.08	0.09	0.411	-0.260	0.106
CIA PHASE 1-2	-0.48					-0.06				
STAFFING_LEVEL	-0.06	0.01	0.000	-0.084	-0.040	0.05	0.01	0.000	0.035	0.056
STAFFING_MIX	-0.30	0.07	0.000	-0.449	-0.156	-0.15	0.03	0.000	-0.216	-0.083
TOTAL RESIDENT	0.01	0.00	0.000	0.012	0.014	0.00	0.06	0.000	-0.379	-0.140
PAYER_TYPE	-2.20	0.17	0.000	-2.529	-1.881	-0.59	0.02	0.000	-0.123	-0.062
IS_CHAIN	-0.11	0.03	0.001	-0.166	-0.045	-0.09	0.00	0.000	0.001	0.003
OCCUPANCY	-3.19	0.12	0.000	-3.426	-2.948	-0.26	0.09	0.000	-0.765	-0.408
FOR_PROFIT	0.52	0.04	0.000	0.439	0.609	0.13	0.02	0.000	0.081	0.172
ACUITY	0.19	0.02	0.000	0.148	0.235	0.24	0.01	0.000	0.219	0.261

	Pressure Ulcer					Catheter Use				
REGION 1 Ref.	1.00					1.00				
REGION 1-2	2.99	0.16	0.000	2.671	3.312	-0.49	0.11	0.000	-0.702	-0.274
REGION 1-3	1.67	0.15	0.000	1.378	1.966	0.33	0.10	0.001	0.136	0.529
REGION 1-4	1.52	0.13	0.000	1.256	1.780	-0.07	0.09	0.403	-0.250	0.100
REGION 1-5	0.63	0.13	0.000	0.377	0.889	1.19	0.09	0.000	1.018	1.358
REGION 1-6	1.45	0.14	0.000	1.168	1.723	0.60	0.09	0.000	0.413	0.779
REGION 1-7	-1.08	0.15	0.000	-1.384	-0.781	1.08	0.10	0.000	0.883	1.274
REGION 1-8	-1.27	0.20	0.000	-1.654	-0.886	1.81	0.13	0.000	1.564	2.062
REGION 1-9	1.13	0.15	0.000	0.830	1.422	-0.10	0.10	0.299	-0.301	0.092
REGION 1-10	0.07	0.21	0.738	-0.345	0.487	1.93	0.14	0.000	1.659	2.207
CONSTANT	12.53	0.41	0.000	11.72	13.347	3.85	0.17	0.000	3.515	4.180

Staffing level. The effect of increasing total staff HPRD[88] showed inconsistent results. Increasing staffing level improved pressure ulcer QMs slightly (-0.06%, $p<0.001$), but worsened catheter use QMs (0.05%, $p<0.001$).

Staffing mix. The effect of increasing the proportion of RN time (represented by staffing mix) showed a small improving effect on both pressure ulcer QMs (-0.30%) and catheter use QMs (-0.15%). The results were significant for both pressure ulcers and catheter use ($p<0.001$).

Payer type. SNFs that were both Medicare and Medicaid certified had improved pressure ulcer and catheter use QMs, as compared to Medicare-only certified SNFs.

For-profit/not-for-profit status. For-profit SNFs had worse QM scores for both pressure ulcers and catheter use, as compared to not-for-profit SNFs (including government owned).

[88] HPRD means hours per resident day and is the measurement method used in this study to measure staffing level. HPRD is determined by the number of hours worked by the collective nursing staff in a 24 hour day divided by the SNF total residents.

Acuity. Resident case-mix acuity showed a small but statistically significant relationship with both pressure ulcer and catheter use QMs in that the higher the acuity the worse the QM scores.

Chain. Whether or not a SNF was part of a chain showed a small, but statistically significant association with pressure ulcer and catheter use QMs. Chain SNFs showed slightly better QMs in this study.

Occupancy Rate. Higher occupancy rates revealed a relatively strong and statistically significant relationship with both pressure ulcer and catheter use QMs. Higher occupancy rates were associated with better SNF quality and thus lower QM scores.

Total residents/SNF Size. The total number of residents in a SNF showed a weak association with both pressure ulcer and catheter use QMs.

Regions. Nearly all of the CMS Regions showed statistically significant associations between both pressure ulcer and catheter use QMs, comparing QM scores from each region to those from Region 1, the reference comparator in this linear regression. This results reporting on Region association means, for example, as shown in **Table 4-11**, that average pressure ulcer QM scores in SNFs from Region 2 were 3.0% higher (worse) than in SNFs from Region 1.

2. Analysis of Continuous Covariates.

Added variable (AV) plot analysis was conducted for each continuous covariate (time period, acuity, occupancy rate, staffing level, staffing mix, and resident total) against pressure ulcer QMs and against catheter use QMs. The AV plot analyses confirmed the appropriateness of using linear regression. AV plots for staffing level and

for staffing mix are shown in **Section 6**, related to the federal mandatory minimum nurse staffing discussion.

3. Interaction Results.

In completing Research Objective Two, I hypothesized, based on the scientific literature discussed in **Chapter 2, Section L**, that interaction terms would likely be necessary because the effect of several covariates (staffing mix, case-mix acuity, and chain status) on QM outputs could be dependent on staffing level.

Table 4-12 below shows the fixed effects results from the mixed effects linear regression analysis where the model included my hypothesized interaction terms.[89] In this case, staffing level and staffing mix did interact for both pressure ulcers and catheter use ($p=0.022$ for pressure ulcers and $p<0.001$ for catheter use). Conversely, staffing level did not interact with acuity in a significant way for catheter use ($p<0.001$ for pressure ulcers and $p=0.073$ for catheter use). Further, whether or not a SNF was part of a chain interacted with staffing level in the catheter use analysis ($p=0.057$ for pressure ulcers and $p<0.001$ for catheter use.) These results indicated that there was interaction between staffing level and staffing mix and some interaction between staffing level and chain, as predicted. However, since the fixed effects coefficients for all of these interaction terms were very small (all less than 0.05% for pressure ulcers and less than 0.07% for catheter use) I concluded that these interactions did not meaningfully impact the study results.

[89] The interaction terms are those with a "#" in the left column.

Table 4-12- Fixed Effects Regression Results with Interaction Terms

	Pressure Ulcer					Catheter Use				
	Coef.	Std. Err.	P>z	[95% Conf. Interval]		Coef.	Std. Err.	P>z	[95% Conf. Interval]	
TIME_PERIOD	-0.18	0.00	0.000	-0.187	-0.183	-0.06	0.00	0.000	-0.059	-0.057
MDS2	1.70	0.03	0.000	1.643	1.756	0.88	0.01	0.000	0.848	0.904
PHASE 0-1	0.72	0.19	0.000	0.347	1.086	-0.13	0.09	0.149	-0.318	0.048
PHASE 0-2	1.20	0.19	0.000	0.817	1.575	-0.07	0.10	0.459	-0.259	0.117
PHASE 1-2	0.48					0.06				
STAFFING_LEVEL	-0.35	0.07	0.000	-0.487	-0.220	0.06	0.03	0.072	-0.005	0.118
STAFFING_LEVEL# STAFFING_MIX	-0.05	0.02	0.022	-0.094	-0.007	-0.07	0.01	0.000	-0.089	-0.049
STAFFING_LEVEL# ACUITY	0.05	0.01	0.000	0.032	0.074	0.01	0.00	0.073	-0.001	0.019
STAFFING_LEVEL #IS_CHAIN	-0.02	0.02	0.414	-0.057	0.024	-0.07	0.01	0.000	-0.091	-0.052
STAFFING_MIX	-0.11	0.11	0.327	-0.327	0.109	0.08	0.05	0.101	-0.015	0.168
RESIDENT TOT.	0.01	0.00	0.000	0.012	0.014	0.00	0.00	0.000	0.001	0.003
PAYER_TYPE	-2.17	0.17	0.000	-2.491	-1.843	-0.58	0.09	0.000	-0.757	-0.400
IS_CHAIN	-0.04	0.08	0.639	-0.205	0.126	0.18	0.04	0.000	0.098	0.256
OCCUPANCY	-3.21	0.12	0.000	-3.447	-2.968	-0.27	0.06	0.000	-0.385	-0.147
FOR_PROFIT	0.52	0.04	0.000	0.439	0.610	0.13	0.02	0.000	0.083	0.174
ACUITY	-0.02	0.05	0.733	-0.109	0.076	0.20	0.02	0.000	0.162	0.247
REGION 1 Ref.	1.00					1.00				
REGION 1-2	3.00	0.16	0.000	2.676	3.316	-0.47	0.11	0.000	-0.687	-0.259
REGION 1-3	1.67	0.15	0.000	1.378	1.965	0.34	0.10	0.001	0.140	0.532
REGION 1-4	1.52	0.13	0.000	1.258	1.782	-0.07	0.09	0.417	-0.248	0.103
REGION 1-5	0.63	0.13	0.000	0.378	0.890	1.19	0.09	0.000	1.024	1.364
REGION 1-6	1.44	0.14	0.000	1.167	1.722	0.60	0.09	0.000	0.420	0.786
REGION 1-7	-1.09	0.15	0.000	-1.392	-0.789	1.08	0.10	0.000	0.886	1.277
REGION 1-8	-1.26	0.20	0.000	-1.648	-0.880	1.83	0.13	0.000	1.576	2.074
REGION 1-9	1.11	0.15	0.000	0.818	1.410	-0.10	0.10	0.305	-0.299	0.094
REGION 1-10	0.07	0.21	0.727	-0.342	0.490	1.94	0.14	0.000	1.662	2.210
CONSTANT	13.69	0.49	0.000	12.729	14.659	3.79	0.22	0.000	3.358	4.224

4. Confounding Analysis Results.

I quantified any potential effects of confounding of covariates on CIA phase by comparing the "total effect" of the CIA phase on the two QMs[90] with the "direct effect"

[90] I leveraged the fixed effects linear regression coefficients in the crude Research Objective One model containing only time period, MDS version, and CIA phase.

of the CIA phase on the two QMs.[91] The net effect[92] of the CIA phase coefficient on the two QM outcomes is shown below in **Table 4-13**, and confirms that there is a small confounding effect of the covariates added in the adjusted Research Objective Two because the net effect is non-zero – i.e., there is a difference in CIA Phase coefficients when the covariates were added into the crude Research Objective One model.

Table 4-13- Effects of Confounding on CIA Phase

	Pressure Ulcer			Catheter Use		
	Crude	Adjusted	Indirect	Crude	Adjusted	Indirect
CIA Phase 0-1	0.90	0.72	-0.18	-0.34	-0.13	0.21
CIA Phase 0-2	1.30	1.20	-0.10	-0.31	-0.08	0.23

5. Ancillary Research Objective Two Results Related to Staffing Level and Staffing Mix as Output Variables.

Given the relationship between staffing level, staffing mix, and quality established in the scientific literature as discussed in **Chapter 2, Section L**, I hypothesized that in response to a CIA and quality monitoring, SNF management would increase staffing levels and improve staffing mix, with the expectation that QM scores would subsequently improve. To explore this hypothesis and to further explore the source of any confounding effects discussed above, I pulled the Research Objective Two model apart and examined the relationships between staffing level, staffing mix, CIAs, and quality by running my linear regression model using both staffing level and staffing mix as output variables.

[91] I leveraged the regression coefficients from the adjusted Research Objective Two model with numerous covariates.
[92] The net effect, also called the "indirect effect" is equal to the crude effect minus the adjusted effect as shown in **Table 4-13**.

Table 4-14 and **Table 4-15** below show the mixed effects linear regression results with staffing levels and staffing mix as the output variables. As evident above in **Chapter 3 Section F**, the statistical models used included just the time period and the CIA phase variables to identify the crude relationship between CIA and staffing levels and staffing mix. I explored the models under four different scenarios to achieve a robust examination of potential CIA/non-CIA effects and timing effects. These scenarios were: (1) baseline - including all SNFs in the regression with no CIA start offset; (2) including only CIA SNFs with no CIA start offset; (3) including all SNFs with an 18 month CIA start offset; and finally (4) including CIA SNFs with an 18 month CIA start offset.

The crude statistical models examining staffing level and staffing mix as outputs, run under the above conditions, resulted in a number of findings. First, the time period coefficient indicated that both staffing level and staffing mix increased slowly but significantly under all scenarios throughout the study period (for staffing level the time period coefficient was 0.006 for all SNFs and 0.009 for CIA SNFs, $p<0.001$; for staffing mix the period coefficient was 0.001 for all SNFs and 0.002 for CIA SNFs, $p<0.001$).

With respect to staffing levels shown in **Table 4-14** below, the "CIA SNF" scenarios resulted in largely *not* significant fixed effects coefficients. The before-to-during CIA phase transition "CIA PHASE 0-1" resulted in *not* significant fixed effects coefficients with the exception of the all-SNF, 18-month offset scenario where $p=0.044$. The before-to-after CIA phase transition "CIA PHASE 0-2" was associated with an approximately 0.2 HPRD increase in staffing level for all SNFs, with no difference between scenarios with or without any CIA start offset.

Table 4-14- Staffing Level as the Outcome Variable, under Four Scenarios

	All SNFs, No offset CIA Phase					CIA SNFs, No offset CIA Phase				
	Coef	Std. Err.	P>z	[95% Conf.	Interval]	Coef	Std. Err.	P>z	[95% Conf.	Interval]
TIME_PERIOD	0.006	0.000	0.000	0.005	0.006	0.009	0.000	0.000	0.008	0.010
CIA_PHASE 0-1	0.045	0.041	0.270	-0.035	0.126	-0.011	0.028	0.703	-0.065	0.044
CIA_PHASE 0-2	0.201	0.043	0.000	0.118	0.285	0.062	0.033	0.063	-0.003	0.127
CONSTANT	3.487	0.093	0.000	3.304	3.670	3.424	0.077	0.000	3.272	3.576
	All SNFs, CIA Phase offset 18 months					CIA SNFs, CIA Phase offset 18 months				
TIME_PERIOD	0.006	0.000	0.000	0.005	0.006	0.009	0.000	0.000	0.008	0.010
CIA_PHASE 0-1	0.071	0.035	0.044	0.002	0.139	0.004	0.025	0.879	-0.044	0.052
CIA_PHASE 0-2	0.227	0.037	0.000	0.154	0.299	0.078	0.032	0.014	0.016	0.140
CONSTANT	3.467	0.093	0.000	3.284	3.650	3.414	0.077	0.000	3.263	3.565

With respect to staffing mix shown in **Table 4-15** below, the before-to-during CIA phase transitions "CIA PHASE 0-1" were associated with a small but positive increase in staffing mix (meaning relatively more RN time) and the associations were significant in nearly all scenarios (the CIA phase coefficient ranged from 0.011 to 0.043, $p=0.006$ or $p<0.001$). Before-to-after CIA phase transitions "CIA PHASE 0-2" were mostly significant – but inconsistent – meaning that all scenarios were associated with positive changes in staffing mix, but CIA SNFs with no CIA start offset showed a not significant association ($p=0.247$). Overall, the before-to-after coefficients were greater than or even with the before-to-during coefficients; this could mean that SNFs increased the proportion of RN time when entering CIAs, and that increase grew or remained constant after the CIAs were completed.

Table 4-15- Staffing Mix as the Outcome Variable, under Four Scenarios

	All SNFs, No offset CIA Phase					CIA SNFs, No offset CIA Phase				
	Coef	Std. Err.	P>z	[95% Conf.	Interval]	Coef	Std. Err.	P>z	[95% Conf.	Interval]
TIME_PERIOD	0.001	0.000	0.000	0.001	0.001	0.002	0.000	0.000	0.002	0.002
CIA_PHASE 0-1	0.026	0.005	0.000	0.016	0.035	0.011	0.004	0.006	0.003	0.018
CIA_PHASE 0-2	0.041	0.005	0.000	0.031	0.051	0.005	0.005	0.247	-0.004	0.014
CONSTANT	0.168	0.011	0.000	0.146	0.189	0.160	0.010	0.000	0.141	0.179
	All SNFs, CIA Phase offset 18 months					CIA SNFs, CIA Phase offset 18 months				
TIME_PERIOD	0.001	0.000	0.000	0.001	0.001	0.002	0.000	0.000	0.002	0.002
CIA_PHASE 0-1	0.043	0.004	0.000	0.035	0.052	0.029	0.003	0.000	0.022	0.036
CIA_PHASE 0-2	0.059	0.005	0.000	0.050	0.068	0.028	0.004	0.000	0.019	0.036
CONSTANT	0.153	0.012	0.000	0.130	0.176	0.148	0.010	0.000	0.129	0.168

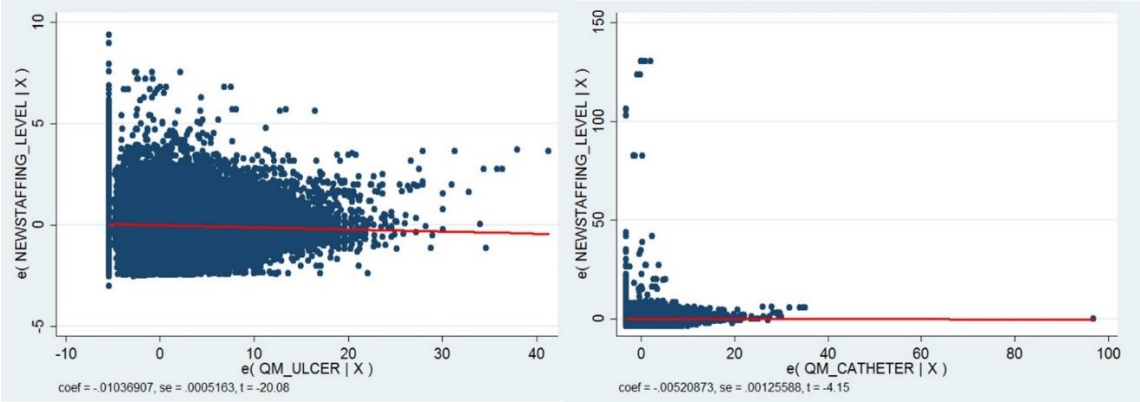
In sum, the limited statistical significance in the staffing level results and the variability in the staffing mix results suggest that CIAs were not significantly associated with positive changes in staffing level but were associated with small but statistically significant changes in staffing mix. The results are in line with the **Explanatory Analysis Figure 4-3** above, which showed average CIA-during staffing levels below average CIA-before staffing levels.

E. *Proposed Federal Mandatory Minimum Nurse Staffing Levels for this Nation's SNFs.*

As discussed in **Chapter 2, Section L** there is currently significant debate surrounding the need for CMS to implement a federal mandatory minimum nurse staffing level for this nation's SNFs. As part of my study, I examined the staffing level data for SNFs that met or exceeded evidenced-based targets for pressure ulcer rates and catheter use rates for long-stay SNF residents to arrive at a proposed federal mandatory minimum nursing staffing level. My approach, to derive a staffing level using QMs, was based on the linear relationship between staffing levels and the QM outcomes; researchers have typically assumed a linear relationship: the higher the numbers of nursing staff available

to provide care the better the quality (Spilsbury, et al., 2011). **Figure 4-13** below confirms the linear relationship in this study with an added variable scatter plots for staffing level and QMs but reverses the axes in order to show staffing level as the output, or dependent variable.

Figure 4-13 – Added Variable Plots Showing Staffing Level as Output Dependent on QMs



As discussed in **Chapter 2, Section H**, the scientific literature and CIA Quality Monitors recommend that SNFs target a pressure ulcer prevalence rate of no more than 5%. Similarly, the recommended indwelling catheter use threshold rate is 2.1%.

To arrive at my proposed mandatory minimum federal nurse staffing standard, I calculated the average staffing levels reported by those SNFs that met or exceeded this 5% target pressure ulcer rate and the 2.1% target catheter use rate. I limited my analysis of staffing data to a three-year look-back period using January 1, 2013 through June 30, 2015 data to ensure the most relevant, consistently reported,[93] and timely staffing recommendation.

[93] Staffing levels were reported to CMS as FTEs through 2012, and then as HPRDs in 2013 and after. Limiting the lookback period to calculate a recommended staffing level avoided any data conversion issues.

Table 4-16 below shows the results from empirical measurement – calculating the average staffing level from SNFs that met or exceeded the two QM target rates and separating the results out by labor category. My results indicated that the average staffing levels for those SNFs (CIA and non-CIA) reporting 5% or lower pressure ulcer rates or 2.1% catheter use rates since January 1, 2013 was approximately 4.0 HPRD. For comparison, I also calculated the staffing level based on linear regression model results, using the constant and the QM coefficient to generate a target staffing rate. The pressure ulcer model result yielded a 3.98 HPRD based on a 5.0 or better pressure ulcer QM and the catheter use model yielded a 3.95 HPRD based on a 2.1 or better catheter use QM. The empirical and model results were consistent and indicated that the average staffing levels for those SNFs meeting or exceeding pressure ulcer and catheter use QM targets were approximately 4.0 HPRD. Therefore, I proposed a federal mandatory minimum nursing staffing level of 4.0 HPRD.[94]

Table 4-16 – Derivation of Proposed Federal Mandatory Minimum Nurse Staffing Levels

	Target QM	Empirical RN Level (HPRD)	Empirical LPN Level (HPRD)	Empirical CNA Level (HPRD)	Empirical Total Level (HPRD)
Pressure Ulcer QM	5.0%	0.761	0.800	2.479	**4.04**
Catheter Use QM	2.1%	0.743	0.810	2.450	**4.00**

F. *Research Objective Three Results Reporting: Main Findings Regarding the Effect of Individual CIAs on SNF Quality, and Regarding the Specific Characteristics of SNFs that showed QM Improvement under their CIAs.*

I had three hypotheses related to Research Objective Three, exploring the effect of individual CIAs on their SNFs' quality. First, because the actual CIA agreements

[94] Given that **Table 4.1** shows that resident case-mix acuity has remained constant in the 2013-to-present timeframe, I did not make any specific acuity adjustment to my staffing level proposal.

applied to SNFs during the study period were fairly standard legal documents with generally uniform requirements (see **Chapter 2, Section 2B1** and **Appendix A**) I expected that there would be minimal differentiation, if any, in QM outcomes based on whether a SNF was under one particular CIA versus another CIA. Second, I hypothesized that my analysis focusing on CIA SNFs only, and excluding the rest of the SNF population (which were all included in Research Objective One), would reveal slightly *more* differentiation than shown in Research Objective One. Third, I hypothesized that those SNFs that showed improvement under CIAs would exhibit distinguishing characteristics related to improved QM outcomes. The Research Objective Three study results confirmed each of my hypotheses at some level.

1. CIA Clustering Results.

Table 4-17 below shows fixed effects results from the mixed effects linear regression analysis using the same crude pressure ulcer model as in Research Objective One, but limiting the analysis to just CIA-covered SNFs. As with the "All SNF" analysis, the "CIA SNF only" analysis produced all significant fixed effects coefficients. The values for the CIA SNF-only analysis, however, were somewhat muted compared to the All SNF population analysis (for example, the CIA Phase 0-1 coefficient changed from 0.90 to 0.75, from the "All SNF" to the "CIA SNF" regression analysis).

Table 4-17- Pressure Ulcer Fixed Effects Regression Results for Research Objective Three

	All SNFs					CIA SNFs				
	Coef.	Std. Err.	P>z	[95% Conf. Interval]		Coef.	Std. Err.	P>z	[95% Conf. Interval]	
TIME_PERIOD	-0.18	0.00	0.000	-0.180	-0.176	-0.18	0.00	0.000	-0.187	-0.170
MDS2	1.71	0.03	0.000	1.659	1.769	1.37	0.09	0.000	1.197	1.539
CIA_PHASE 0-1	0.90	0.16	0.000	0.586	1.218	0.75	0.17	0.000	0.421	1.085
CIA_PHASE 0-2	1.30	0.17	0.000	0.976	1.630	0.98	0.21	0.000	0.574	1.377
CIA_PHASE 1-2	0.40					0.22				
CONSTANT	13.10	0.34	0.000	12.426	13.774	13.68	0.40	0.000	12.896	14.470

Table 4-18 below shows the random effects pressure ulcer analysis results focusing on just CIA SNFs, and reveals a slightly greater variance explained by CIAs (5.9% correlation in the CIA-only analysis compared to 3.5% in the All-SNFs analysis). This finding is consistent with my expectation that CIA might explain slightly more QM variance without the non-CIA population of SNFs being grouped into "CIA 0." Nonetheless, the variance in QM scores explained by CIA is still much less than the variance in QM score explained by SNF/provider number.

Table 4-18- Pressure Ulcer Random Effects Regression Results for Research Objective Three

	ALL SNFs					CIA SNFs				
	Estimate	Std. Err.	[95% Conf. Interval]		Correlation	Estimate	Std. Err.	[95% Conf. Interval]		Correlation
CIA variance	1.335	0.716	0.466	3.822	3.5%	2.101	1.262	0.647	6.821	5.9%
PROVNUMBER variance	12.728	0.168	12.403	13.061	33.3%	9.408	0.407	8.642	10.241	26.5%
RESIDUAL variance	24.160	0.052	24.058	24.263		23.955	0.155	23.653	24.262	

Table 4-19 below shows the fixed effects results from the mixed effects linear regression analysis using the same crude catheter use model as in Research Objective One, but again limiting the analysis to just CIA-covered SNFs. Unlike the "All SNF" analysis, the "CIA SNF only" analysis produced a statistically insignificant result for the

CIA before-to-during transition coefficient (p=0.836). Further, the sign (direction) of the CIA before-to-after coefficient changed (from -0.31 to +0.46), indicating QM worsening instead of an improvement.[95]

Table 4-19- Catheter Use Fixed Effects Regression Results for Research Objective Three

	ALL SNFs					CIA SNFs				
	Coef.	Std. Err.	P>z	[95% Conf. Interval]		Coef.	Std. Err.	P>z	[95% Conf. Interval]	
TIME_PERIOD	-0.06	0.00	0.000	-0.058	-0.056	-0.08	0.00	0.000	-0.088	-0.079
MDS2	0.89	0.01	0.000	0.866	0.921	0.56	0.05	0.000	0.469	0.646
CIA_PHASE 0-1	-0.34	0.08	0.000	-0.504	-0.178	-0.02	0.09	0.836	-0.189	0.153
CIA_PHASE 0-2	-0.31	0.09	0.000	-0.483	-0.145	0.46	0.11	0.000	0.250	0.664
CIA_PHASE 1-2	0.03					0.47				
CONSTANT	5.92	0.18	0.000	5.566	6.275	6.35	0.22	0.000	5.929	6.777

Table 4-20 below lists the random effects catheter use analysis results focusing on just CIA SNFs, and reveals a slightly greater variance explained by CIAs (4.6% correlation in the CIA-only analysis compared to 4.0% in the "All SNFs" analysis). This finding is consistent with my expectation that CIAs might explain slightly more QM variance without the non-CIA population of SNFs being grouped into "CIA zero." However, as with pressure ulcers, the catheter use variance in QM score explained by CIAs was still much less than the variance in QM score explained by SNF/provider number.

[95] These results indicate that there could have been other variables confounding the catheter use results – confounding that was not apparent in the Research Objective One analysis with the non-CIA population included.

Table 4-20- Catheter Use Random Effects Regression Results for Research Objective Three

	ALL SNFs					CIA SNFs				
	Estimate	Std. Err.	[95% Conf. Interval]		Correlation	Estimate	Std. Err.	[95% Conf. Interval]		Correlation
CIA variance	0.306				4.0%	0.525	0.271	0.191	1.444	4.6%
PROVNUMBER variance	5.133				41.0%	3.728	0.153	3.441	4.040	32.6%
RESIDUAL variance	7.383					7.185	0.044	7.099	7.271	

2. Results Reporting on which CIAs Showed CIA-Phase Improvement.

The next set of results reporting for Research Objective Three relates to capturing the effect of individual CIAs on SNF quality. Each of the rows in **Table 4-21** below corresponds to a CIA in the dataset, and details how many SNFs that CIA covers, how many observations appear in the dataset for that CIA, and provides the fixed effects coefficient results from the Research Objective One model, when the model was re-run and *limited to just that single CIA*. The "0-1" column in **Table 4-21** lists the coefficient results for the before-to-during CIA transition, and the "0-2" column lists the coefficient results for the before-to-after CIA transition. The p-value columns indicate the statistical significance of the model results when run for each CIA individually. The "Const." column provides the constant (B_0) from the regression to give a relative sense for the impact of the CIA phase coefficient. For example, for CIA 6 and CIA 7 the before-to-after transition coefficients indicate strong association between CIA phase and QM (-7.8 and -3.2, respectively). However, the constants for those two regression results (32.8 and 12.8, respectively) indicate that with or without the CIA phase influence, the SNFs under those CIAs reported very poor quality, as determined by pressure ulcer QMs.

There are a number of cases in **Table 4-21** below where coefficients were not available (NA). The two primary reasons why many coefficients were not available are:

(1) "small n," especially for the single SNF CIAs; and (2) gaps in the data. Data gaps, such as when a CIA started before the study period so that there are not any before-CIA QM data, are discussed in detail in **Section G3** of this Chapter.

The last column in **Table 4-21** below indicates which of the CIAs demonstrated statistically significant QM improvement during either the before-to-during CIA transition or the before-to-after CIA transition, for either pressure ulcer or catheter use QMs. Those improved CIAs are highlighted in yellow. SNFs subject to the CIAs with a checkmark were then flagged in the study dataset with a 1 in the CIA_IMPROVE variable in preparation for the analysis described in **Section 3** below.

Table 4-21 - Fixed Effects Regression Results for each Individual CIA

		Pressure Ulcers						Catheter Use						
CIA	**SNFs**	**Obs**	**0-1**	**P-value**	**0-2**	**P-value**	**Const.**	**Obs**	**0-1**	**P-value**	**0-2**	**P-value**	**Const.**	**Improved**
1	159	5509	NA	NA	0.69	0.009	13.67	5871	NA	NA	0.22	0.130	6.48	
2	1	37	NA	NA	0.84	0.587	6.64	37	NA	NA	-1.01	0.352	0.86	
3	201	6592	NA	NA	-0.32	0.227	14.22	7371	NA	NA	-0.06	0.667	5.62	
4	275	9652	NA	NA	0.58	0.006	13.94	10531	NA	NA	0.42	0.000	6.35	
5	1	42	NA	NA	0.61	0.808	17.31	42	NA	NA	0.96	0.586	26.68	
6	1	42	NA	NA	-7.84	0.000	32.76	42	NA	NA	1.96	0.003	5.67	✓
7	10	402	NA	NA	-3.17	0.002	12.79	402	NA	NA	-1.74	0.000	4.84	✓
8	1	43	NA	NA	3.13	0.468	24.96	43	NA	NA	1.49	0.014	7.51	
9	1	43	3.91	0.075	4.23	0.167	19.70	43	1.42	0.143	4.78	0.000	3.53	
10	1	39	3.79	0.130	-5.34	0.191	0.81	39	0.24	0.717	-1.56	0.142	1.80	
11	1	39	-2.67	0.290	1.17	0.800	15.66	39	0.22	0.664	1.09	0.249	1.91	
12	1	19	NA	NA	NA	NA	21.37	43	3.10	0.034	3.62	0.140	9.08	
13	2	83	2.42	0.098	6.35	0.039	12.51	83	-0.63	0.233	0.70	0.533	2.67	
14	1	33	-0.69	0.800	-6.74	0.198	14.24	33	2.45	0.006	6.12	0.000	4.19	
15	1	43	1.15	0.684	-7.29	0.141	9.49	43	-0.74	0.365	-0.76	0.592	3.38	
16	23	766	1.24	0.151	2.67	0.044	14.70	918	0.65	0.114	-0.14	0.829	6.47	
17	1	40	-0.57	0.762	-7.82	0.010	11.94	40	-1.29	0.191	1.57	0.318	11.96	✓
18	2	51	3.23	0.146	NA	NA	6.30	68	-2.25	0.010	NA	NA	2.10	✓
19	1	40	-1.70	0.455	-9.11	0.045	9.45	40	3.86	0.000	7.40	0.000	4.05	✓
20	1	21	NA	NA	NA	NA	8.64	21	NA	NA	NA	NA	10.69	
21	1	41	-0.64	0.785	NA	NA	16.62	42	-1.27	0.253	NA	NA	10.73	
22	1	21	NA	NA	NA	NA	10.83	20	NA	NA	NA	NA	-9.32	
23	1	36	-5.30	0.173	NA	NA	-40.30	36	-0.32	0.714	NA	NA	6.75	
24	1	35	0.85	0.663	-3.61	0.413	14.28	35	0.16	0.791	-1.02	0.452	2.02	

			Pressure Ulcers						Catheter Use					
25	1	43	3.06	0.279	1.90	0.763	10.24	43	-1.38	0.198	-1.18	0.621	0.76	
27	1	8	NA	NA	NA	NA	-41.10	24	2.67	0.164	NA	NA	1.27	
28	1	10	NA	NA	-1.66	0.302	7.67	9	NA	NA	1.09	0.166	9.84	
30	131	4571	1.97	0.000	NA	NA	14.07	4961	0.16	0.349	NA	NA	8.58	
32	426	13838	NA	NA	-0.40	0.011	11.65	16269	NA	NA	-0.04	0.619	6.24	✓
33	1	42	NA	NA	1.06	0.699	10.61	42	NA	NA	1.28	0.138	-3.03	
34	65	1714	NA	NA	-0.44	0.345	14.00	2199	NA	NA	0.25	0.213	5.85	
35	1	24	NA	NA	16.13	0.001	64.81	41	NA	NA	4.60	0.001	15.74	
38	4	92	-3.10	0.153	-2.55	0.473	20.05	123	-0.33	0.751	-1.66	0.330	10.89	
40	5	204	-2.88	0.005	-4.07	0.093	21.89	204	-0.70	0.143	-0.14	0.899	6.02	✓
41	5	201	-0.31	0.848	-1.56	0.605	15.78	202	0.32	0.658	1.54	0.261	4.69	
42	3	98	-5.76	0.004	-10.51	0.018	9.18	110	-1.34	0.046	-1.98	0.222	3.10	✓
43	2	87	3.69	0.057	0.88	0.838	9.35	88	-1.71	0.191	-2.68	0.359	7.65	
44	1	21	NA	NA	NA	NA	6.53	38	-2.64	0.066	NA	NA	8.25	
45	1	16	5.41	0.253	7.29	0.300	9.46	23	-0.19	0.825	-1.85	0.003	3.92	✓
46	3	120	-0.24	0.869	-0.45	0.840	9.44	124	-1.27	0.175	-1.45	0.308	3.88	
47	10	255	0.49	0.708	NA	NA	15.99	374	-0.34	0.394	NA	NA	4.55	
48	7	240	-0.75	0.503	NA	NA	7.60	243	-3.21	0.000	NA	NA	3.31	✓
50	3	127	1.98	0.289	-9.63	0.001	11.94	127	-0.49	0.578	0.53	0.756	5.06	✓

3. Ancillary Objective Three Results reporting on SNF characteristics subject to CIAs that showed QM improvement.

The final section of results reporting for Research Objective Three relates to reporting the specific characteristics of the SNFs that showed quality improvement under their CIAs. This next step in Research Objective Three assessed if any of these SNF characteristics could be associated with the CIAs where the SNFs improved. My hypotheses related to this Ancillary Objective were that staffing level and staffing mix would be most strongly associated with CIA responsiveness to SNF quality improvements.

Table 4-22 below lists the results from this assessment of SNF characteristics, where logistic regression was used to evaluate the relationships between SNF characteristics and whether the SNF was covered by a CIA that showed QM improvement. Each odds ratio in **Table 4-22** indicates the odds, after adjusting for the other covariates, that a SNF was covered by a CIA that improved in either pressure ulcers or catheter use QMs. For example, considering staffing level, a SNF with one additional HPRD has a 14.8% lower odds of being subject to an improving CIA, holding all other covariates constant. The **Table 4-22** results are ordered with the strongest indicators at the top (those with odds ratios farthest from 1.0) and weakest at the bottom. I kept the Region indicators together but ordered them from strongest to weakest as well.

Table 4-22 – SNF Characteristics Related to CIA QM Improvement

	CIA Improvement				
	Odds Ratio	Std. Err.	P>z	[95% Conf. Interval]	
FOR_PROFIT	3.429	0.206	0.000	3.048	3.858
OCCUPANCY	2.864	0.263	0.000	2.392	3.430
PAYER_TYPE	1.736	0.184	0.000	1.410	2.137
STAFFING_MIX	1.284	0.090	0.000	1.120	1.473
ACUITY	1.071	0.021	0.000	1.031	1.113

	CIA Improvement				
RESTOT	0.996	0.000	0.000	0.996	0.997
STAFFING_LEVEL	0.852	0.013	0.000	0.827	0.877
IS_CHAIN	0.658	0.020	0.000	0.620	0.699
REGION 1-7	15.288	0.911	0.000	13.602	17.182
REGION 1-3	6.700	0.328	0.000	6.086	7.375
REGION 1-9	2.372	0.112	0.000	2.162	2.602
REGION 1-5	2.260	0.102	0.000	2.069	2.469
REGION 1-4	1.978	0.091	0.000	1.808	2.164
REGION 1-8	1.882	0.117	0.000	1.665	2.127
REGION 1-6	1.363	0.074	0.000	1.226	1.515
REGION 1-2	1.359	0.255	0.101	0.942	1.962
REGION 1-1 (Ref.)	1.000				
REGION 1-10	0.671	0.052	0.000	0.576	0.782
CONSTANT	0.060	0.010	0.000	0.043	0.083

The results of this logistic regression analysis showed that all of the covariates (except Region 1-2) exhibited a statistically significantly relationship with the CIA improvement indicator.

For-profit/not-for-profit status. For-profit SNFs had 3.43 times higher odds of being in an improving CIA than not-for-profit SNFs (including government owned).

Occupancy Rate. A SNF with a 1% higher occupancy rate had 2.86 times higher odds of being in an improving CIA.

Payer type. SNFs that were both Medicare and Medicaid certified had 1.74 times higher odds of being in an improving CIA than Medicare-only SNFs.

Staffing mix. A SNF with a 1% higher proportion of RN HPRD had 28.4% higher odds of being in an improving CIA.

Acuity. A SNF with one additional unit of acuity (either ADL, transfer, or eating) had 7.1% higher odds of being in an improving CIA.

Total residents/SNF Size. A SNF with one additional resident had a 0.4% lower odds of being in an improving CIA.

Staffing level. A SNF with one additional HPRD had 14.8% lower odds of being in an improving CIA.

Chain. Chain SNFs had 34.2% lower odds of being in an improving CIA.

CMS Regions. With the exception of comparing Region 2 to Region 1, all of the regional comparisons (comparing each region to Region 1) produced statistically significant results. For example, SNFs in Region 7 had 15.3 times higher odds of being in an improving CIA than SNFs in Region 1.

These results suggest that adjusting occupancy, staffing mix, and acuity are three factors that SNF organizations can adjust to increase their odds of improving quality under their CIA.

In sum, the Research Objective Three results confirm my hypotheses that CIAs are not highly differentiated based on the CIA clustering analysis. The similar variance shown on the CIA clustering – whether including just CIA SNFs or the entire SNF population – suggests that CIA differentiation in terms of QMs is not significant. The second component of Research Objective Three that manually grouped CIAs for regression and logistic regression analysis did suggest three SNF characteristics – occupancy, staffing mix, and acuity – as possibly associated with a greater likelihood of SNF QM improvement once a SNF has entered a CIA.

G. Analysis of SNF Attrition, Missing Values, and CIA Phase Data Gaps.

1. SNF Attrition.

During the timeframe of this study from Q4 2003 through to Q2 2015, approximately 464 SNFs were lost to attrition. **Figure 4-14** below shows a histogram of the number of SNFs that dropped out by year. **Figure 4-14** also differentiates SNF dropouts by those subject to a CIA and those who dropped out and were not subject to a CIA. Importantly, there were 14 SNFs subject to a CIA that dropped out (which is only 0.1% of the total CIA SNF population), and each of these 14 CIA SNFs dropped out long after its CIA ended (from 1.5 to 6 years).

Figure 4-14 – SNF Dropouts by Year and whether they were subject to a CIA

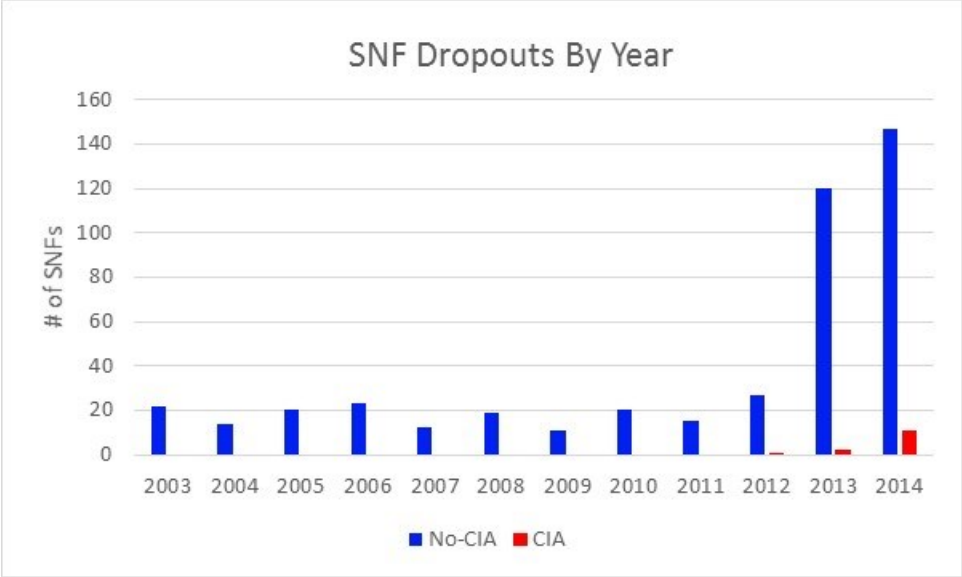


Table 4-23 below shows that there was a relationship between SNFs that dropped out and whether the SNF was subject to a CIA: CIA SNFs had a lower proportion of dropouts (0.73% compared to 1.36% for non-CIA SNFs). **Table 4-23** below also shows

that smaller SNFs with fewer than 30 residents[96] had a higher proportion of dropouts (5.98% compared to 1.09% for SNFs with more than 30 residents).

Table 4-23 – Relationships Between SNF Dropout, CIAs, and SNF Resident Total

Drop Outs		CIA		SNF Resident Total		
		No CIA	CIA	< 30	>= 30	Total
No	#	540,415	59,023	24,604	574,834	599,438
	%	98.64%	99.27%	94.02%	98.91%	98.70%
Yes	#	7,476	433	1,566	6,343	7,909
	%	1.36%	0.73%	5.98%	1.09%	1.30%
Total		547,891	59,456	26,170	581,177	607,347

Tables 4-24 and 4-25 below compare dropout SNF QMs against non-dropout SNF QMs, and differentiate between CIA and non-CIA covered SNFs. For pressure ulcers QMs in **Table 4-24**, there was not a statistically significant difference between dropouts and non-dropouts (p=0.196 and p=0.145, respectively), whether I examined CIA SNFs or non-CIA SNFs, meaning that the SNFs that dropped out had no statistically significant impact on pressure ulcer QM outcomes.

Table 4-24 –Pressure Ulcer QMs for Dropouts and non-Dropouts; CIA and non-CIA SNFs

Pressure Ulcer QMs		No CIA	CIA
Non-Dropouts	Mean	9.586%	9.774%
	Obs	387,554	48,759
Dropouts	Mean	9.434%	10.402%
	Obs	3,448	232
	Difference	0.153%	0.628%
	P-value	0.196	0.145

However, for catheter use QMs shown in **Table 4-25** below, there was a small but statistically significant difference in the dropout SNFs, in that QMs for SNF dropouts were about 0.25% worse (higher) in non-CIA SNFs, but were 1.5% worse in the CIA SNFs. While this catheter use result could potentially be concerning, given that the dropouts occurred long after the SNFs completed the relevant CIAs, and given that only

[96] I selected SNFs with 30 or fewer residents as a "proxy" for small SNFs.

14 CIA SNFs were affected by dropouts, I concluded that SNF dropouts did not meaningfully affect the results of my Three Research Objectives.

Table 4-25 – Catheter Use QMs for Dropouts and non-Dropouts; CIA and non-CIA SNFs

Catheter Use QMs		No CIA	CIA
Non-Dropouts	Mean	4.725%	4.965%
	Obs	472,036	54,711
Dropouts	Mean	4.984%	6.468%
	Obs	4,905	345
	Difference	-0.259%	-1.502%
	P-value	<0.001	<0.001

2. Missing Values.

In addition to SNF attrition, there were also missing values in the study dataset. **Table 4-26** below lists several covariates and outcome variables and the corresponding percentage of missing values for each variable.

Table 4-26 – Key Variables and percent missing

Variable	# Missing Records	% Missing Records
STAFFING_MIX	4,951	0.8%
STAFFING LEVEL	3,617	0.6%
ACUITY	41,157	6.8%
QM_ULCER	167,405	27.6%
QM_CATHETER	75,395	12.4%

While the missing SNF structural characteristics values for staffing level, staffing mix, and acuity are all acceptably low, the percent of missing QM outcome variables is somewhat concerning. I hypothesized that the majority of the missing QM data was due to the fact that CMS does not report QM values for SNFs that have fewer than 30 residents in the denominator of interest for that QM. CMS specifically does not publish QM values (small denominator suppression)[97] where the number of residents in the relevant QM denominator is less than 30.

[97] CMS encourages SNFs to report QMs even if they have fewer than 30 residents in the relevant denominator, but CMS will replace long-stay QM values with "199" if there are fewer than 30 residents

Chi^2 results in **Table 4-27** below show the association between the SNF resident total, defined by the under30 variable, where smaller than a 30-residents population was reported, and missing pressure ulcer and missing catheter use QMs. Results clearly support my hypothesis that database records from smaller SNFs are more likely to lack QM data (88.9% compared to 24.8% for pressure ulcers and 86.4% compared to 9.1% for catheter use).

Table 4-27 – Relationship Between SNF Resident Total and Missing QM data

Resident Total		Pressure Ulcers		Catheter Use		
		Not Missing	Missing	Not Missing	Missing	Total
< 30	#	2,920	23,271	3,551	22,640	26,191
	%	11.15%	88.85%	13.56	86.44	100%
>= 30	#	437,088	144,134	528,467	52,755	581,222
	%	75.20%	24.80%	90.92%	9.08%	100%
Total		440,008	167,405	532,018	75,395	607,413

Next, I examined the relationship between SNF CIA coverage and missing QM data. The **Table 4-28** Chi^2 results below show that for both pressure ulcers and catheter use QMs, a relatively smaller portion of CIA SNFs reported missing data compared to non-CIA SNFs (17.7% for CIA SNFs compared to 28.6% for non-CIA SNFs for pressure ulcers and 7.5% for CIA SNFs compared to 12.9% for non-CIA SNFs for catheter use).

Table 4-28 – Relationship Between CIA Coverage and Missing QM Data

CIA		Pressure Ulcers		Catheter Use		
		Not Missing	Missing	Not Missing	Missing	Total
Yes	#	48,879	10,510	54,949	4,440	59,389
	%	82.30%	17.70%	92.52%	7.48%	100%
No	#	391,129	156,895	477,069	70,955	548,024
	%	71.37%	28.63%	87.05%	12.95%	100%
Total		440,008	167,405	532,018	75,395	607,413

represented in the SNF data submission. *See* Data Dictionary and data file layout descriptions available at https://data.medicare.gov, accessed on November 25, 2015.

Logically, at this point I have shown that the CIA SNF analysis conducted was relatively unaffected by missing data, since most of the missing data is associated with small SNFs, and most of the CIAs are not associated with small SNFs.

To examine how the pressure ulcer and catheter use QM scores would have affected my analyses (if the QM scores had not been missing,) I used two sets of T-tests, examining the difference between QM scores for CIA SNFs and non-CIA SNFs, and for small and "not-small" SNFs. **Table 4-29** below shows the results from two T-tests, for CIA-covered SNFs and non-CIA covered SNFs, each comparing pressure ulcer QMs from SNFs with fewer than 30 residents with QMs from larger SNFs. The T-test results show that there is a large difference (smaller SNFs had 8.3 percentage points better QM scores for the available data in the dataset) between pressure ulcer QMs in SNFs with fewer residents compared to QMs in larger SNFs. Notably, the results are the same whether examining CIA covered SNFs or non-CIA covered SNFs (8.3% is close to 7.9%.)

Table 4-29 – Relationship Between Pressure Ulcer QMs, CIA Coverage, and SNF Resident Total

Pressure Ulcer QMs		No CIA	CIA
< 30 Residents	Mean	1.360%	1.868%
	Obs	2,844	76
>= 30 Residents	Mean	9.646%	9.785%
	Obs	388,285	48,803
	Difference	8.286%	7.917%
	P-value	<0.001	<0.001

Table 4-30 below shows results from similar T-tests comparing catheter use QMs from SNFs with fewer than 30 residents with QMs from larger SNFs. Again, the T-test results show that there is a significant difference (smaller SNFs had approximately 3.3 percentage points better QM scores for SNFs with available data) between catheter use QMs in SNFs with fewer than 30 residents compared to QMs in larger SNFs. Again, the

results are similar whether examining CIA covered SNFs or non-CIA covered SNFs (3.3% is close to 3.5%).

Table 4-30 – Relationship Between Catheter Use QMs, CIA Coverage, and SNF Resident Total

Catheter Use QMs		No CIA	CIA
< 30 Residents	Mean	1.473%	1.446%
	Obs	3,453	98
>= 30 Residents	Mean	4.752%	4.990%
	Obs	473,616	54,851
	Difference	3.279%	3.544%
	P-value	<0.001	<0.001

In sum, for both pressure ulcer and catheter use QMs, my analysis suggests that missing data is concentrated among small SNFs where CIAs have relatively less coverage. Further, if the missing QM data were to be imputed, this imputed data would likely be similar to the data from smaller SNFs, and therefore be comprised of lower QM scores (meaning better, more improved quality). Without the missing data, the SNF QM data are artificially high (worse), and in particular, the non-CIA covered SNF QM data are artificially high. Therefore, my analyses in this study which examined the differences between two QMs in CIA-covered SNFs as compared to non-CIA covered SNFs is conservative. That is to say, if there were less missing data, there would be more, lower, non-CIA SNF QM scores and therefore the difference between non-CIA SNFs and CIA SNFs would be more pronounced.

3. CIA Phase Data Gaps.

Table 4-31 below details the CIA Phase Data Gap challenge, listing each CIA, the number of SNFs covered by the CIA, its start and end dates, and how many time periods (quarters) were recorded in the dataset for those CIA-covered SNFs. Of particular note in **Table 4-31** is the disparity in the number of SNFs covered by different CIAs: compare the 24 single-facility SNF CIAs (more than half the total CIAs) to the

large chain CIAs like Mariner Health (275 SNFs) or Beverly Enterprises (426 SNFs). While this study explored clustering and differentiation between CIAs in Research Objective 3, **Table 4-31** makes it clear that comparing CIAs was challenging because of the unequal CIA sizes.[98]

Table 4-31 – CIA Listing with Counts of Measures by Phase

CIA	SNFs	CIA Start	CIA End	CIA Entity	Before	During	After	Total
1	163	20-Apr-01	01-Jan-08	VENCOR, INC.		2287	3674	5961
2	1	12-Dec-01	18-Sep-06	NATIONAL HEALTHCARE CORPORATION – JOPLIN		9	32	41
3	201	28-Feb-02	22-Aug-07	SUN HEALTHCARE GROUP, INC.		2424	4723	7147
4	275	03-Apr-02	07-Sep-07	MARINER HEALTH CARE, INC.		3564	6901	10465
5	1	12-Jul-02	08-Nov-05	SUBURBAN WOODS, LLC.		8	36	44
6	1	13-Dec-02	16-Oct-06	WOODBINE HEALTHCARE AND REHABILITATION CENTRE		12	32	44
7	10	01-Aug-03	16-Dec-08	AMERICAN HEALTHCARE, L.L.C.		194	228	422
8	1	21-Aug-03	01-Mar-07	MARY J. DREXEL HOME		14	31	45
9	1	29-Jun-04	02-Apr-08	MAJESTIC OAKS NURSING HOME	2	17	26	45
10	1	28-Oct-05	12-Feb-09	HARBOR HEALTHCARE AND REHABILITATION CENTER	8	14	20	42
11	1	20-Dec-05	03-Mar-11	LIFE CARE CENTER OF LAWRENCEVILLE	8	20	13	41
12	1	04-May-06	15-Jul-09	PLUM GROVE PALATINE, LLC			21	21
13	2	10-Jul-06	06-Jan-12	ATHENA HEALTH CARE ASSOCIATES, INC.	17	42	26	85
14	1	04-Aug-06	03-Nov-09	LOCHEARN NURSING HOME, LLC	12	10	17	39
15	1	14-Feb-07	15-Jul-10	BRIGHTEN AT BROOMALL	13	15	17	45
16	23	02-Aug-07	05-Dec-12	CIENA HEALTHCARE MANAGEMENT, INC.	227	383	217	827
17	1	27-Nov-07	20-Jul-09	IHS/UNIHEALTH POST-ACUTE CARE OF MONCKS CORNER, INC	16	8	18	42
18	2	04-Jan-08	26-Oct-11	A & C HEALTH CARE SERVICES, INC.	9	18	28	55
19	1	07-Feb-08	16-Jun-11	G & R ALAMEDA HEALTHCARE SERVICES, LLC	9	17	16	42
20	1	07-Feb-08	17-Oct-11	COUNTRY VILLA NOVATO HEALTHCARE CENTER, LLC		13	10	23
21	1	21-Mar-08	26-Oct-11	CORONA CARE CONVALESCENT CORPORATION	9	20	14	43
22	1	02-Apr-08	22-Jul-11	CORINTHIAN SUBACUTE HEALTHCARE CENTER, INC.		11	10	21
23	1	25-Apr-08	17-Oct-11	NORWALK SKILLED NURSING & WELLNESS CENTRE, LLC	9	19	14	42

[98] The statistical model in Research Objective One did not specifically account for CIA size in the gamma (γ) term.

CIA	SNFs	CIA Start	CIA End	CIA Entity	Before	During	After	Total
24	1	19-May-08	22-Jul-11	INTEGRATED NURSING AND REHABILITATION CARE OF GLEN	9	17	15	41
25	1	23-Jun-08	22-Jul-11	INTEGRATED NURSING AND REHABILITATION OF PERRIS, INC	9	21	15	45
27	1	04-Sep-08	12-Mar-12	HIGHLAND PARK SKILLED NURSING & WELLNESS CENTRE, L		2	8	10
28	1	21-Nov-08	02-Apr-12	COUNTRY VILLA PARK AVENUE HEALTHCARE CENTER, LLC		8	12	20
30	131	26-Sep-14	25-Sep-19	EXTENDICARE	4450	446		4896
32	426	03-Feb-00	28-Aug-08	BEVERLY ENTERPRISES, INC.		6424	8412	14836
33	1	29-Oct-01	01-Jun-07	TWIN OAKS NURSING HOME, INC.		15	30	45
34	67	09-Sep-03	16-Dec-09	IHS/LTC-FUNDAMENTAL LONG TERM CARE HOLDINGS, INC.		925	970	1895
35	1	09-Sep-03	27-Sep-13	IHS/EXCEPTIONAL CARE, L.L.C.		19	7	26
38	4	22-Nov-05	07-Jul-09	IHS/THCI, INC.	16	35	64	115
40	5	01-May-07	16-Sep-11	GREEN ACRES	41	103	70	214
41	5	30-Oct-07	20-Jan-11	LIFEHOUSE HEALTH SERVICES, LLC	45	90	82	217
42	3	02-Jan-08	29-Apr-11	INFINITY GROUP	22	46	44	112
43	2	07-Feb-08	13-Jul-11	NAZARETH ENTERPRISES, INC.	17	42	30	89
44	1	07-Feb-08	17-Oct-11	PETALUMA SKILLED NURSING & WELLNESS CENTRE, LLC		11	12	23
45	1	14-Mar-08	12-Mar-12	ISOCARE SNF, INC.	2	14	8	24
46	3	06-Jan-10	16-Nov-12	CATHEDRAL ROCK	71	27	30	128
47	10	06-Jun-14	06-Jun-19	FOUNDATION HEALTH SERVICES, INC	244	32		276
48	7	21-Dec-12	21-Dec-17	GGNSC HOLDINGS LLC	194	152		346
50	3	06-Mar-06	05-Mar-11	PLEASANT CARE	54	110	96	260
	1366			Total Measurements	5513	17658	26029	49200

Chapter V: Discussion of Results and Policy Implications.

This Discussion of Results and Policy Implications Chapter summarizes key findings, discusses findings in the context of the scientific literature, offers policy recommendations to improve the effect of quality of care CIAs on SNF quality and to set a federal mandatory minimum nurse staffing level, and addresses study strengths, limitations and implications for future research. Specifically, this Discussion Chapter is divided into four sections: (1) discussion of the key findings on my Three Research Objectives, in light of existing literature on SNF quality; (2) discussion of policy implications and recommendations to improve the effect of quality of care CIAs on SNF quality and to set a federal mandatory minimum nurse staffing level. Of note, this Section of the Chapter addresses recommendations to improve the CIA document itself, recommendations to improve the 'During CIA' monitoring process, and critically, recommendations to create a new 'Post-CIA' follow-up process; (3) study strengths and limitations; and finally (4) implications and suggestions for future research on the effectiveness of CIAs on SNF quality and on defining a staffing model to improve SNF quality of care.

A. Summary Discussion of Key Findings on the Three Research Objectives.

This Section first addresses the pronounced secular trends that were occurring in SNF quality during the timeframe of this study, as measured by pressure ulcer and catheter use QMs, and then discusses the key findings on my Three Research Objectives. A summary table at the end of **Section A.1** of this Chapter illustrates my hypotheses, conclusions, and evidentiary support for these conclusions on each Research Objective (see **Table 5-1)**.

During the time period of this study, from 2003 to 2015, the explanatory data show that there was a pronounced secular trend of pressure ulcer and catheter use quality measure improvement nationwide, as discussed in detail in **Chapter 4, Section B.3**.[99] One explanation for this improving secular trend could be the new CMS guidance and quality improvement initiatives that were rolled out during the study period, as discussed in **Chapter 2, Section J**. While there has been a trend of secular improvement in pressure ulcer and catheter use QMs over the course of this study, QM scores have not improved to the desired threshold levels. While the desired threshold for SNF pressure ulcer rates is 5%, the national average for SNF pressure ulcer rates in 2015 was 6.0%. While the desired threshold for catheter use rates is 2.1%, the national average for catheter use rates in 2015 was 3.1% (Rantz, et al., 2000, Renz, 2015 interview on the issue of desired threshold rates).

Over this same time period from 2003 through 2015, the explanatory data also show that there was a narrowing of the difference between CIA and non-CIA pressure ulcer and catheter use QMs, as discussed in detail in **Chapter 4, Section B.** Specifically, toward the end of this study period, the CIA and non-CIA SNF pressure ulcer QMs as well as the CIA and non-CIA catheter use QMs appear to have been converging, i.e., the difference between both sets of CIA and non-CIA QMs was getting narrower over time.[100] Also during the timeframe of this study, there was a change in instrumentation

[99] Linear regression confirmed that nationally, on average since 2003, pressure ulcer scores have improved 0.2% every quarter and catheter use scores have improved 0.05% every quarter ($p<0.001$).

[100] This finding is with the exception of the 2013 time period for pressure ulcer QMs, and with the exception of the 2011-2013 time period for catheter use QMs. One possible explanation for this narrowing difference with the pressure ulcer QMs is **detection bias**, meaning that once a SNF is under a CIA, there is greater scrutiny paid to correctly identifying all stages of pressure ulcers and therefore CIA SNFs have increased their pressure ulcer rates and are meeting the non-CIA SNF rates. An obvious caution with this potential explanation is that the later study period years, as shown in the explanatory data graphs, do not necessarily equate to all SNFs being under or recently having completed their CIAs.

from MDS 2.0 to MDS 3.0. The shift from MDS 2.0 to MDS 3.0 resulted in an average improvement in QMs of about 2% for pressure ulcers and 1% for catheter use.

It is against the backdrop of these secular, converging trends and the MDS shift that this study found that CIAs did not have a significant positive effect on SNF quality, as measured by pressure ulcer and catheter use QMs. This study also found mixed results for whether staffing levels and staffing mix had a positive effect on SNF quality or on the effect of CIAs on SNF quality. Additionally, this study found that the SNF characteristics of payer type (if a facility is paid by both Medicare and Medicaid), if a SNF was part of a chain, and if a SNF had a high occupancy rate, all had improving impacts on pressure ulcer and catheter QMs. Further, this study found that for-profit status, high acuity, and having a higher number of total residents had worsening impacts on pressure ulcer and catheter use QMs. Additionally, this study found that a SNF's assignment to a particular CIA did not well explain pressure ulcer and catheter use QM variance. Finally, this study found that on an individualized CIA analysis basis, occupancy rate, staffing mix, acuity, for-profit status, and payment status were all associated with CIA responsiveness and improved QMs during a SNF's CIA period, and in some cases after the term was completed. The **Summary Table of Conclusions on Research Objectives - Table 5-1** below addresses these findings in more detail.

Table 5-1 - Summary Table of Conclusions on Research Objectives

	Objective	Hypothesis	Conclusion	Results that Support the Conclusion
Research Objective One	To assess whether quality CIAs had a positive effect on SNF quality of care, as measured by pressure ulcer and indwelling catheter use quality measures.	A SNF would improve its two QM scores some time before entering and during the pendency of its quality CIA, but the SNF's QM scores would worsen at some point after the CIA expired.	CIAs were not associated with improvements in pressure ulcer QMs but CIAs did have a very small positive association with catheter use QMs. Further, the correlation of QM scores within SNFs was significant but the correlation of QM scores within CIAs was not significant.	**Table 4-4** shows pressure ulcer mixed effects linear regression results, indicating an increase (worsening) in pressure ulcer QMs of 0.90% when a SNF enters a CIA, and an increase of 1.30% when a SNF exits the CIA. **Table 4-5** shows that clustering on CIA explains 3.5% of pressure ulcer QM variance while clustering on provider number explains 33.3%. $P < 0.001$ in all cases. **Table 4-6** shows catheter use mixed effects linear regression results, indicating a decrease (improvement) in catheter use QMs of -0.34% when a SNF enters a CIA, and a decrease of -0.31% when a SNF exits the CIA; **Table 4-7** shows that clustering on CIA explains 4.0% of catheter use QM variance while clustering on provider number explains 41.0%. $P < 0.001$ in all cases.

	Objective	Hypothesis	Conclusion	Results that Support the Conclusion
Ancillary Research Objective One	To determine <u>when</u> any CIA effect occurred relative to the official start date of the CIA.	SNF chains (as opposed to single facility SNFs) would exhibit quality improvements related to CIA negotiations 18 to 36 months before the official start date and formal commencement of the quality CIA.	Varying the starting point of the QM analyses from baseline, when the CIA actually started, to 18 months and then 36 months before the CIA actually started, did not significantly influence when any CIA effect occurred.	**Table 4-9** lists pressure ulcer regression coefficients with time offsets on the CIA Phase (either baseline with zero offset, 18-month, or 36-month offset), and shows that the CIA phase coefficients for chain SNFs did get smaller (0.60 compared to 1.02, meaning less QM worsening) with a longer time offset, but there was still no QM improvement associated with CIAs, even when measured with a time offset. P <0.001 for the 18-month offset, but p=0.77 for the 36-month offset. **Table 4-10** lists catheter use regression coefficients with CIA Phase time offsets, and shows that chain SNFs exhibited a greater QM improvement with an 18 month offset (-0.89 CIA phase coefficient compared to -0.45), but actually then showed the same QM improvement with a 36 month offset (-0.88). P < 0.001 in all cases.

	Objective	Hypothesis	Conclusion	Results that Support the Conclusion
Research Objective Two	To assess how certain SNF characteristics influenced quality and/or the effect of quality CIAs on SNF quality of care.	Most SNF structural factors will not influence quality of care or the effect of a CIA on SNF quality of care, but staffing levels and staffing mix will positively influence quality of care and the effect of a CIA on SNF quality of care. Further, SNF resident case-mix acuity will influence quality of care and the effect of a CIA on SNF quality of care in that, holding all other factors constant, higher resident case-mix acuity will negatively influence the effect of a quality CIA on SNF quality of care.	Increased staffing levels and staffing mix were associated with improved pressure ulcer QM scores but at a lower magnitude than expected. Payer type, whether or not a SNF was part of a chain, and occupancy rate also were associated with improving pressure ulcer QMs. For profit, acuity, and total residents had negative associations. By contrast, for catheter use, staffing level and staffing mix showed no association in direction or magnitude. Payer type, whether or not a SNF was part of a chain, and occupancy rate also were associated with improving catheter use QMs. For profit, acuity, and total residents had negative or negligible associations.	**Table 4-11** shows results from an adjusted regression model (with the full set of covariates.) The covariates (staffing level, staffing mix, payer type, chain indicator, occupancy rate, for profit, acuity, total residents, and the CMS Regions) had a diluting effect on the magnitude of the CIA phase coefficients from the crude model. For pressure ulcer QMs, staffing level (-0.06), staffing mix (-0.30), payer type (-2.20), chain indicator (-0.11), and occupancy (-3.19) all had positive quality-improving effects (Medicare and Medicaid were associated with better QMs than Medicare-certified only; chain SNFs and higher occupancy were associated with better QMs.) For profit (0.52), acuity (0.19), and total residents (0.01) were associated with worsening quality. For catheter use QMs, staffing mix (-0.15), payer type (-0.59), chain indicator (-0.09), and occupancy (-0.26) all had positive quality-improving effects (Medicare and Medicaid were associated with better QMs than Medicare-certified only; chain SNFs, and higher occupancy were associated with better QMs.) Staffing level (0.05), for profit (0.13), and acuity (0.24) were associated with worsening quality. Total residents (0.00) had a negligible effect.

	Objective	Hypothesis	Conclusion	Results that Support the Conclusion
Ancillary Research Objective Two	To examine the relationships among staffing level, staffing mix, and CIAs.	In response to a CIA, SNF management would increase staffing levels and improve staffing mix, with the expectation that QM scores would subsequently improve.	CIAs were not significantly associated with positive changes in staffing level but were associated with small but statistically significant changes in staffing mix. This conclusion was developed by regression analyses for staffing level and staffing mix under four scenarios: a baseline with all SNFs; a CIA-only regression excluding non-CIA covered SNFs; an all-SNF regression with an 18-month offset to the CIA start dates; and a CIA-covered SNF only regression with an 18 month CIA start date offset.	**Table 4-14** shows that staffing levels rose throughout the study period (the time period coefficient ranged from 0.006 to 0.009), but that the initiation of CIAs was not significantly associated with increases in staffing level. In the baseline scenario, the CIA Phase 0-1 coefficient for staffing level was 0.045 but $p = 0.270$. The other three scenario results were similar, meaning that none of the regression results showed a significant increase in staffing level associated with CIAs. **Table 4-15** shows that improved staffing mix also rose slowly throughout the study period (the time period coefficient was between 0.001 and 0.002), and that the initiation of CIAs was associated with increases in staffing mix. In the baseline scenario, the CIA Phase 0-1 coefficient for staffing mix was 0.026 and $p < 0.001$. The all-SNF 18-month offset scenario showed a greater association between CIA and staffing mix (0.043, $p < 0.001$), which may indicate that SNF management began increasing the proportion of RN time in advance of CIAs actually starting.

	Objective	Hypothesis	Conclusion	Results that Support the Conclusion
Research Objective Three	To explore the effect of individual CIAs on their SNFs' quality.	Individual CIA characteristics would not explain the variance in QM outcomes because the vast majority of CIA requirements are standardized from CIA to CIA. Analysis focusing on CIA SNFs only and excluding the rest of the SNF population (as in Research Objective One), would reveal more differentiation between CIAs than shown in Research Objective One.	CIAs did not well explain pressure ulcer and catheter use QM variance. But analyses focusing only on CIA-covered SNFs were consistent with the full SNF population analyses for pressure ulcers. Catheter use CIA-only regressions associated smaller improvements and catheter use worsening with CIAs. Further, segregating QM regression analyses to one CIA at a time did serve to identify those CIAs whose SNFs improved their QMs in any CIA phase in a statistically significant way, but results were incomplete because several CIAs covered a single or small number of SNFs with limited data across all CIA phases.	**Table 4-17** compares pressure ulcer QM crude regression results between the full set of all SNFs and the set of CIA-covered SNFs. These results confirm that limiting analysis to CIA-covered SNFs does not change the association between CIAs and QMs (e.g., the CIA Phase 0-1 coefficient was 0.75 compared to 0.90 in the all-SNF regression.). **Table 4-19** shows a similar comparison for catheter use QMs, but the CIA-only results do not comport with the all-SNF results. For the CIA Phase 0-1 transition, the CIA-only regression shows a -0.02 coefficient with p=0.836; for the CIA Phase 0-2 transition, the CIA-only coefficient shows a positive (worsening) 0.46 with p <0.001. **Table 4-21** lists results from crude regression analyses for pressure ulcer and catheter use QMs, where the regression was constrained to SNFs covered by each individual CIA, one at a time. **Table 4-21** shows 11 CIAs that exhibited either pressure ulcer or catheter use improvement in any CIA phase with p≤0.05.

	Objective	Hypothesis	Conclusion	Results that Support the Conclusion
Ancillary Research Objective Three	To examine the specific characteristics of those SNFs that showed improvement under their CIAs in any CIA phase.	Staffing level and staffing mix would be most strongly associated with CIA responsiveness to SNF quality improvements.	Certain SNF characteristics, i.e., occupancy, staffing mix, and acuity, were associated with CIA responsiveness, and are factors that SNFs could adjust to increase their odds of being associated with CIA quality improvement during or after their CIA.	**Table 4-22** lists results from the logistic regression analysis comparing covariate factors for SNFs covered by the 11 CIAs identified in **Table 4-21**. Among predictors that SNFs could change, Occupancy (OR 2.86), staffing mix (OR 1.28), and acuity (OR 1.07) are most strongly associated with a greater likelihood of CIA QM improvement once a SNF has entered a CIA.

1. Discussion of Research Objective One Results.

Research Objective One was to assess whether quality CIAs had a positive effect on SNF quality of care, as measured by pressure ulcer and indwelling catheter use quality measure (QM) scores. I hypothesized that a SNF would improve these two QM scores some time before entering and during the pendency of its quality CIA, but that the SNF's QM scores would worsen at some point after the CIA period ended. Contrary to my hypothesis, this study found that CIAs did not have a significant positive effect on SNF quality of care. Specifically, CIAs did not have a positive effect on pressure ulcer QMs; in fact, pressure ulcer QMs worsened during the CIA and worsened further after the CIA period ended. By contrast, CIAs did have a very small positive effect on catheter use QMs and this very small improvement trend also continued after the CIA period ended. Further, the study found that the correlation of pressure ulcer and catheter use QM scores within SNFs was significant, but that the correlation of these QM scores within CIAs was not significant, meaning that which CIA a SNF was assigned to did not influence that SNF's QM scores.

There are several possible explanations for these findings. In the first instance, the different outcomes for pressure ulcer and catheter QMs could be attributed to the different way in which the presence of pressure ulcers and indwelling catheters are detected. There is subjectivity and skill involved in measuring and staging a pressure ulcer whereas it is objectively clear whether a resident has or does not have an indwelling catheter. Also, under the CIA, improved clinical education and care processes might have produced improved catheter use outcomes more rapidly than pressure ulcer outcomes. Therefore, changes in SNF staffing, clinical processes, and the degree of outside monitoring could have differing effects on the two QMs, as discussed below.

There are several possible explanations for the finding that pressure ulcer QMs worsened after the CIA began. First, these findings could be attributable to detection bias before the CIA period, in that SNF clinical staff either did not know how to detect and record pressure ulcers (particularly Stage I and II ulcers which could be more challenging to diagnose) or the SNF clinical staff were intentionally avoiding recording pressure ulcers because of expected regulatory enforcement (reporting bias). Second, and relatedly, during the CIA period, after the clinical staff were educated in the processes of detecting and staging pressure ulcers and were being monitored to ensure that their reporting was accurate, it was only then that the true and accurate higher pressure ulcer rates were identified. This reporting bias explanation is consistent with the literature which attributed MDS measurement errors in studies to SNF under-documenting adverse events or clinical conditions in order to avoid regulatory sanctions. (Wu, et al., 2009, Ranham, et al., 2009).

A third explanation for this finding that pressure ulcer QMs worsened during the CIA is selection bias, in that once a facility is under a CIA, and this is publically known (as discussed in **Chapter 3**, all active CIAs are public documents available on the HHS-OIG website), the facility is then unable to get the resident referrals that it once did and is forced to take on residents that have more comorbidities (like pressure ulcers) that other SNFs do not want to admit. Therefore, during the CIA, the SNFs could be admitting residents with more pressure ulcers or with greater risk factors for pressure ulcers. A fourth, somewhat related explanation for the worsening pressure ulcer study finding is that once the CIA becomes public it may become difficult for the facility to attract the best qualified staff. This may also explain why pressure ulcer scores worsened during the CIA (negative unintended consequences of the CIA).

A fifth explanation for this finding is that, under the CIA, a SNF may be working to improve a number of QMs, such as falls, antipsychotic use, medication errors, etc., and does not have the bandwidth to improve on all QMs; therefore, by working to improve many care processes, pressure ulcer rates are allowed to rise. A sixth related and somewhat counterintuitive explanation for a rise in pressure ulcer rates is that, given that CIAs are costly for the SNF (the cost of the Quality Monitor and the tracking and trending, etc.), the SNF could have to cut costs in terms of staffing and supplies in order to be able to afford the CIA costs and therefore, these further unintended consequences of the CIA could cause worsening pressure ulcers rates.

The finding that pressure ulcer rates worsened further after the CIA period ended is consistent with my hypothesis that SNFs would not maintain any structural and process improvements gained during the CIA period. This is because in some cases, the SNF

corporate culture had not fundamentally changed during the CIA, and after the CIA ends, the SNF is no longer monitored on a frequent basis to enforce those structural and process quality improvement changes. This finding is consistent with the literature which found, in the CMS Special Focus Facility Report (SFF Report), that once a SNF graduated from the SFF Program, relapse on surveys and obtaining survey deficiencies was common. (CMS SFF Study). Further my study finding is consistent with the 2009 HHS-OIG CIA Report which found that the SNF industry considered many of the CIA requirements to be costly and burdensome. Specifically, the industry found the CIA to be costly given the time and effort required for compliance, the costs of developing and implementing new policies and procedures, the cost of implementing change across often 'silo-ed' departments within the SNF corporation, and the additional staff required to meet CIA requirements.[101] It is therefore likely that once the CIA period ends, if the SNF corporation is no longer monitored, it could cease to engage in previous CIA-driven structural and process improvements.

The finding that the correlation of QM scores within CIAs was not significant (meaning which CIA a SNF was assigned to did not influence that SNF's QM scores) is not surprising given that many CIA documents and Quality Monitor approaches are currently fairly standard; therefore, the quality improvement approach that SNF corporations and single facility SNFs experience in this CIA process is generally similar and not differentiated by CIA.

[101] *See* 2009 HHS-OIG CIA Report and Solution Brief, "Corporate Integrity Agreements," *MetricStream* (May 27, 2014).

a. Ancillary Research Objective One Result Discussion.

Ancillary Research Objective One was to determine when any CIA effect occurred relative to the official start date of the CIA. I hypothesized that SNF chains (as opposed to single facility SNFs) would exhibit quality improvements related to a typically lengthy government investigation and CIA negotiation 18 to 36 months before the actual start date and formal commencement of the quality CIA. My study did not support this hypothesis. Varying the starting point of the QM analyses from baseline, when the CIA actually started, to 18 months and then 36 months before the CIA actually started, did not significantly influence when any CIA effect and/or improvement occurred. This finding is contrary to the experience of government experts, clinicians, and Quality Monitors who maintain that SNF chains do typically begin to show some QM improvement between one and three years before the commencement of the CIA, depending on the length of the federal government investigation pre-CIA.[102]

2. Discussion of Research Objective Two Results.

Research Objective Two was to assess how certain SNF structural factors influenced quality and/or the effect of quality CIAs on SNF quality of care. I hypothesized that most SNF structural factors would not influence quality of care or the effect of a CIA on SNF quality of care, but that staffing levels and staffing mix would positively influence quality of care and the effect of a CIA on SNF quality of care. Further, I expected that SNF resident case-mix acuity would influence quality of care and the effect of a CIA on SNF quality of care in that, holding all other factors constant,

[102] Telephone interview with Dr. Sue Renz (December 28, 2015), and telephone interview with Dr. David Zimmerman (December 30, 2015).

higher resident case-mix acuity would negatively influence the effect of a quality CIA on SNF quality of care.

The study found that the introduction of the SNF covariates into an adjusted model had a diluting effect and reduced the magnitude of the CIA phase coefficients from the Research Objective One results. The pressure ulcer results became "less worse" in the transition from before-to-during the CIA, and the catheter use results got "less improved" in the transition from before-to-during the CIA. These results of the effect of the SNF covariates on the effect of the CIA on quality further reinforce the Research Objective One results that CIAs had limited, if any, impact on SNF quality, but rather other SNF factors were driving quality changes.

The study found that certain covariates were associated with positive QM effects while others were negatively associated with QM effects for pressure ulcers and catheter use. The study found that increased staffing levels and improved staffing mix were associated with improved pressure ulcer QM scores but at a much lower magnitude than expected. Payer type (both Medicare and Medicaid payer), that a SNF was part of a chain, and a higher occupancy rate were also associated with positive impacts on pressure ulcer QMs. That a SNF was for-profit, had higher acuity, and had higher total SNF residents were associated with negative impacts (small effect) on pressure ulcer QMs.

By contrast, for indwelling catheter use, staffing level and staffing mix showed a very small negative association with QM scores. Payer type (both Medicare and Medicaid payer,) that a SNF was part of a chain, and a higher occupancy rate had improving impacts on catheter use QMs. While for-profit and higher acuity had worsening impacts on catheter use QMs, total SNF residents had negligible impacts on

catheter use QMs. As shown in **Table 5-2** below, the Research Objective Two results related to the effect of the study covariates on SNF quality were generally consistent with the literature.

Table 5-2 – Research Objective Two results – effect of the covariates on SNF quality

Factor	Results	Consistent with Literature?
Staffing Level	Increasing staffing level improved pressure ulcer QMs slightly (0.06%, p<0.001), but worsened catheter use QMs (0.05%, p<0.001).	This pressure ulcer finding was consistent with several studies: Xing, et al., 2013, Harrington, et al., 2014, Bostick, et al., 2006, Castle, 2008, and Hyer et al., 2011, but the catheter use finding was not consistent with Castle, 2008.
Staffing Mix	Increasing the proportion of RN time (represented by staffing mix) showed an improving effect on both pressure ulcer (-0.30%) and catheter use (-0.15%) QMs. The results were significant for both pressure ulcers and catheter use (p<0.001).	This finding was consistent with Xing, et al., 2013, and Konetzka, et al., 2008.
Payer Type	SNFs that were **both** Medicare and Medicaid certified had **improved pressure ulcer and catheter use QMs**.	This finding was consistent with Kash, et al., 2009, and Shippee, et al., 2015.
For-profit/not-for-profit status	For-profit SNFs had worse QM scores for both pressure ulcers and catheter use, as compared to not-for-profit SNFs (including government owned).	This finding was consistent with Harrington, et al., 2014, Kash, et al., 2009, Shippee, et al., 2015, Xing, et al., 2013, and Hillmer, et al., 2005.
Acuity	Resident case-mix acuity showed a small but statistically significant relationship with both pressure ulcer and catheter use QMs in that the higher the acuity the worse the QM scores.	This finding was consistent with Kash, et al., 2009, and Wan, et al. 2006.
Chain	Whether or not a SNF was part of a chain showed a small, but statistically significant influence on pressure ulcer and catheter use QMs. Chain SNFs showed slightly better QMs in this study.	This finding was not consistent with Harrington, et al., 2014
Occupancy Rate	Higher occupancy rates revealed a relatively strong and statistically significant relationship with both pressure ulcer and catheter use QMs. Higher occupancy rates were associated with better SNF quality and thus lower QM scores.	This finding was consistent with Decker, et al., and 2008, Zinn, et al., 2005.
Total Residents	The number of residents in a SNF showed a weak worsening association with both pressure ulcer and catheter use QMs.	This finding was consistent with Harrington, et al., 2014, where larger facilities had worse QM scores.

As shown in **Table 5-2**, this study's findings that staffing mix and staffing levels and numerous SNF characteristics were associated with changes in pressure and catheter use QMs are consistent with several scientific studies which addressed organizational

characteristics of SNFs and their associations with quality outcomes (Castle, et al., 2007, Harrington, et al., 2003, Grabowski, et al., 2001). Specifically, this study's finding that increased staffing levels and a greater RN ratio in the staffing mix were associated with improved pressure ulcer quality is generally consistent with the literature. (Castle, et al., 2007, Harrington, et al., 2003, Grabowski, et al., 2001). Other studies have found that SNFs with higher levels of nurse staffing have better QM performance, as do SNFs with higher skilled nursing staff ratios (Xing, et al., 2013). In particular, high nurse staffing hours have been associated with improved care and resident outcomes for functional abilities, pressure ulcers, weight loss and other measures of quality (Harrington, et al., 2014, Bostick, et al., 2006, Castle, 2008, and Hyer et al., 2011). Further, a higher RN staffing mix has been associated with fewer pressure ulcers and less catheterization (Konetzka, et al., 2008).

This study's finding that payer type (both Medicare and Medicaid payer, as opposed to just Medicare), and a higher occupancy rate had improving impacts on QMs is consistent with the literature. The literature generally supports that nursing facilities providing skilled care with a higher Medicare census, and with more Medicare resident days are associated with better QM scores (Kash, et al., 2009, Shippee, et al., 2015). Further, several studies have found that higher-occupancy facilities report better QM scores. (Decker, et al., 2008, Zinn, et al., 2005).

This study's findings that profit status and higher acuity are associated with worsening QMs is also consistent with the literature. Several recent studies indicated that the nation's largest for-profit SNFs deliver significantly lower quality care than non-profit SNFs, as measured by QMs. (Harrington, et al., 2014, Kash, et al., 2009, Shippee,

et al., 2015, Xing, et al., 2013, Hillmer, et al., 2005). In 2005, Hillmer, et al., conducted a comprehensive literature review of 38 studies from 1990 to 2002 which concluded that quality was lower in for-profit SNFs (Hillmer, et al., 2005). Further, a higher resident case-mix acuity has been associated with poorer SNF QM scores (Kash, et al., 2009, Wan, et al. 2006).

By contrast, this study's finding that a SNF being part of a chain is associated with improved QMs is not consistent with the current literature. The Harrington, et al., study found that with shareholder pressure for short term profitability, nursing home chains exert control on labor costs which result in lower staffing and poorer SNF quality (Harrington, et al., 2014). Harrington, et al., found that because of the large chains' marketing, outreach and contracting capacity, large chains may have less concern about competing on the basis of quality than non-chains. *Id.* Further, regulatory fines associated with poor quality could be small in comparison to the resources available to a chain and therefore be less of a deterrent. *Id.*

This difference in findings between my study and the literature on the "chain" characteristic may be partially explained by the fact that my study defined "chain" as two or more facilities, whereas the literature with contrary findings typically defined SNF chains to include the largest 10 to 12 chains in the nation (Harrington, et al., 2014) which have more than 100 facilities per chain. The profit motive and incentives of large 100+ facility chains are likely different from those facilities that are part of a two or three facility SNF chain.

a. Ancillary Research Objective Two Results Discussion.

Ancillary Research Objective Two was to examine the relationships among staffing level, staffing mix, and CIAs. I hypothesized that in response to a CIA, SNF

management would increase staffing levels and improve staffing mix, with the expectation that QM scores would subsequently improve. Contrary to this expectation, the study found that CIAs were not significantly associated with positive changes in staffing level, but were associated with small but statistically significant changes in staffing mix. This conclusion was developed by regression analyses for staffing level and staffing mix under multiple sets of conditions as described in **Table 5-1** above. One explanation for this result is that in response to the urging of the Quality Monitor, the SNF may hire more RNs (and thereby improve staffing mix). However, the SNF does not increase its overall budget for staffing. Therefore, staffing levels do not increase, and the hiring of more RNs potentially leads to the termination of other SNF staff. This explanation has support in the literature (Chen, et al., 2015).

b. Findings on Federal Mandatory Minimum Staffing Level.

An additional finding of this study was that a federal mandatory minimum staffing level should be established and should be set at 4.0 HPRD[103] (the rationale for this 4.0 HPRD level is discussed in detail in **Chapter 4, Section E**). In **Section B.4** of this Chapter, the policy recommendation to set 4.0 HPRD as the federal mandatory minimum standard is discussed in detail.

3. Discussion of Research Objective Three Results.

Research Objective Three was to explore the effect of individual CIAs on its SNFs' quality of care. I hypothesized that the individual CIA analysis would not better explain the variance in QM outcomes because the vast majority of CIA requirements are

[103] It should be noted here that, as shown in **Chapter 4 Table 4-1**, the average staffing level for non-CIA SNFs in the 2009 to 2015 time period has reached 4.0 HPRD at various points but is not consistent across the states which have widely varying staffing requirements.

standardized from CIA to CIA. I further hypothesized that an analysis focusing only on CIA SNFs and excluding the rest of the SNF population (that was included in Research Objective One), would reveal slightly more differentiation in QM scores among CIAs than found in Research Objective One.

Generally consistent with my hypothesis, Research Objective Three results showed that assignment to a specific CIA did not well explain pressure ulcer and catheter use QM variance.[104] The likely explanation for this outcome is that most CIAs have predominantly standardized language and do not identify any specific care problem areas that the SNFs need to address. Therefore, the implementation of CIAs through Quality Monitors at the SNFs proceed similarly and mute any corporate effect associated with a particular CIA.

While the study did not find significant correlation by CIA in the SNF-only analysis, in the CIA-by-CIA analysis, this study did find that certain CIAs that gave specific clinical direction to the Quality Monitor did have an effect on pressure ulcer QMs. As shown in **Table 5-3** below, nine of the eleven CIAs that showed improvement in any CIA phase had specific and unique CIA language that served to direct the Quality Monitor's focus and may have contributed to QM improvement under the CIA.

[104] Of note, for pressure ulcers, analyses focusing on CIA-covered SNFs only were consistent with the full SNF population analyses where pressure ulcer QMs worsened during the CIAs. By contrast, catheter use QMs behaved differently in the CIA-only regression than in the full SNF population analyses. For catheter use, CIA-only regressions associated smaller improvements during the CIA than did the all-SNF catheter analyses and then associated even less catheter use improvement after the CIA period had ended. Further, segregating QM regression analyses to one CIA at a time did serve to identify those CIAs where the SNFs improved their QMs in any CIA phase in a statistically significant way, but results were incomplete because several CIAs covered a single or small number of SNFs with limited data across all CIA phases (particularly the before phase).

Table 5-3 – Table of Specific CIA Provisions for CIA-SNFs Showing Improvement in a CIA Phase

CIA #	Corporate Entity/Provider name	Unique CIA Agreement Language Directing the Quality Monitor's Focus
17	IHS/UNIHEALTH POST-ACUTE CARE OF MONCKS CORNER, INC	The IHS CIA required Monitors to: • Ensure that use of Chemical & Physical Restraints is pursuant to acceptable professional standards, including measures designed to ensure that psychotropic medication is used only in accordance with accepted professional standards and only where there is an appropriate psychiatric or neuropsychiatric diagnosis, and that psychotropic medication is never used as punishment, in lieu of a training program, for behavior control or in lieu of a psychiatric or neuropsychiatric diagnosis or for the convenience of staff. • Ensure that IHS provides appropriate wound care (decubitus ulcer) treatment and appropriate nutrition for residents with wounds. • Ensure that residents shall be protected from being victimized by other aggressive residents.
18	A & C HEALTH CARE SERVICES, INC.	The A&C CIA required Monitors to: • Ensure that Provider has an appropriate and effective protocol designed to prevent falls by patients and residents, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans. • Ensure that Provider has a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect. • Ensure that Provider complies with California's staffing requirements set out in California Health and Safety Code section 1276.5.
19	G & R ALAMEDA HEALTHCARE SERVICES, LLC	The G&R CIA required Monitors to: • Ensure that Provider has an appropriate and effective protocol designed to prevent falls by patients and residents, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans. • Ensure that Provider has a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect. • Ensure that Provider complies with California's staffing requirements set out in California Health and Safety Code section 1276.5.
32	BEVERLY ENTERPRISES, INC.	The Beverly Amendment required Monitors to: • Ensure that Provider has a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.

CIA #	Corporate Entity/Provider name	Unique CIA Agreement Language Directing the Quality Monitor's Focus
40	GREEN ACRES	The Green Acres CIA required Monitors to: • Ensure that residents receive effective and appropriate wound care (decubitus ulcer) prevention and treatment that meets or exceeds the Agency for Healthcare Research and Quality (formerly, Agency for Health Care Policy and Research) Clinical Practice Guidelines for the Prediction, Prevention and Treatment of Pressure Ulcers (Guidelines). • Ensure that an effective and appropriate protocol is developed and implemented to identify residents who are or have been diagnosed with diabetes and are at high risk of developing complications related to diabetes.
42	INFINITY GROUP	The Infinity CIA required Monitors to: • Ensure that Provider has an appropriate and effective protocol designed to prevent falls by patients and residents, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans. • Ensure that Provider has a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect. • Ensure that Provider complies with California's staffing requirements set out in California Health and Safety Code section 1276.5.
45	ISOCARE SNF, INC.	The IsoCare CIA required Monitors to: • Ensure that Provider has an appropriate and effective protocol designed to prevent falls by patients and residents, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans. • Measures designed to ensure that there is a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, neglect, wounds that do not heal or are not treated properly, failure of dietary and nutrition services, failure to provide appropriate diabetic care, and failure to provide appropriate restorative care to residents.

CIA #	Corporate Entity/Provider name	Unique CIA Agreement Language Directing the Quality Monitor's Focus
48	GGNSC HOLDINGS LLC	The GGNSC CIA required Monitors to: • Completing accurate clinical assessments as required by applicable Federal law, which shall include: (1) that all resident care information be recorded in ink or permanent print; (2) that corrections shall only be made in accordance with accepted health information management standards; (3) that erasures shall not be allowable; and (4) that clinical records may not be rewritten. • Use of prescribed and supervised turning schedules for turning and positioning each non-ambulatory resident at least every two hours, or more often if medically indicated (unless documented in the resident's record as contrary to medical advice of resident's treating physician), including provision for sufficient number of nursing assistants to accomplish the turning schedules, as determined by each facility's Director of Nursing. • Use of proper pressure-relieving devices, including, but not limited to, pressure pads, specialized mattresses, pillows, heel protectors, and foot cradles. • Assessment of each resident upon admission for existing pressure ulcers or being at risk for developing pressure ulcers and, for each resident who has pressure ulcers or is at risk of developing pressure ulcers, performing a risk and causation assessment to develop preventative measures to avoid bruises, skin tears, and pressure ulcers. • Assessment and documentation by a licensed registered nurse of the risk and cause of each pressure ulcer, bruise, and skin tear, and development of a care plan to help prevent further deterioration of bruises, skin tears, or pressure ulcers from occurring. • Appropriate treatment of skin tears and pressure ulcers, including accurate and regular documentation of pressure ulcers. • Use of color photographs for all Stage III and Stage IV pressure ulcers upon discovery and weekly thereafter or more often if significant changes occur. • Prompt communication with the resident's family member or legal representative, and with the resident's treating physician, of new skin tears, bruises, and pressure ulcers and of the improvement or worsening over time.
50	PLEASANT CARE	The Pleasant Care CIA required Monitors to: • Ensure that Provider has an appropriate and effective protocol designed to prevent falls by patients and residents, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans. • Ensure that Provider has a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect. • Ensure that Provider complies with California's staffing requirements set out in California Health and Safety Code section 1276.5.

a. Ancillary Research Objective Three Results Discussion.

Ancillary Research Objective Three was to examine the specific characteristics of those individual SNFs that showed QM improvement under individual CIAs in any CIA phase. I hypothesized that staffing level and staffing mix would be most strongly associated with CIA responsiveness to SNF quality improvements. Mostly supporting my hypothesis, the study found that staffing mix, occupancy rate, and acuity were associated with CIA responsiveness,[105] and are factors that SNFs could adjust during the CIA process to increase the likelihood that CIAs would result in quality improvement. Contrary to my hypothesis, staffing level was not positively associated with CIA responsiveness.

B. Discussion of Policy Implications and Recommendations to Improve the Effect of Quality CIAs on SNF Quality and to set a Federal Mandatory Minimum Staffing Level.

This study found that CIAs do not have a significant positive effect on SNF quality, as measured by pressure ulcer and catheter use QMs. In order to increase the effectiveness that CIAs could have on SNF corporations and single facility SNFs, changes to the CIA process should be made in three areas. First, the CIA document itself should be improved by including more prescriptive and concrete requirements. Second, the CIA monitoring process should be improved by again requiring the Quality Monitor to engage in more specific and measurable monitoring activities. And third, and most importantly, a post-CIA monitoring process should be developed which would hold SNFs to account for two years post-CIA, and which would use the full force of remedies

[105] Note, that in this Research Question Three analysis, these SNF characteristics were associated with QM improvement in SNFs under individual CIAs and so these results do not address the same questions asked and do not yield the same results as Research Objective Two.

available to the federal government if a SNF or SNF corporation fails to improve its care quality. Finally, given that the scientific literature and this study's staffing analysis found that increased staffing levels are associated with improvement in QM scores (for this study a very small improvement), a federal mandatory minimum staffing number should be adopted to ensure that SNFs staff facilities to an acceptable threshold level. This Section of the **Discussion Chapter** addresses these four policy recommendations in detail.

1. Recommendations to Improve the CIA Document.

As discussed in detail in **Chapter 2, Section B**, there has been an evolution in the nature of the CIA document from 2000 to the present. The very first CIA documents in the 2000 timeframe contained a bare minimum of provisions designed to ensure that a SNF met federal regulatory requirements in caring for its residents, and to identify the specific care processes that a SNF corporation or the SNF facility needed to improve under the CIA. After this first generation of CIAs, the vast majority of CIAs from the 2001 to 2004 timeframe introduced a number of boilerplate provisions dedicated to billing and reporting accuracy. In 2007, a number of quality CIAs began to include specific clinical quality compliance provisions. And finally, in the current generation of CIAs, from 2011 to the present, the CIAs have included much more prescriptive detail related to clinical care and physical plant requirements.

In order to improve and increase the effectiveness of CIAs on SNF quality, the CIA document should further evolve to include more prescriptive detail specifically related to clinical care and SNF self-monitoring. It is very important to note that the Research Objective Three analysis showed that the CIAs that were associated with

pressure ulcer improvement (as detailed in **Chapter 4, Section F.2**) had specific CIA language related to pressure ulcer clinical care.

The Green Acres SNF entered into its CIA on May 1, 2007. Over the course of its CIA, its pressure ulcer QMs improved by 3 percentage points (improving on average from 22% to 19%). The Green Acres CIA contained the following unique CIA language related to pressure ulcers:

> Ensure that residents receive effective and appropriate wound care (decubitus ulcer) prevention and treatment that meets or exceeds the Agency for Healthcare Research and Quality (formerly, Agency for Health Care Policy and Research) Clinical Practice Guidelines for the Prediction, Prevention and Treatment of Pressure Ulcers (Guidelines).

Similarly, the IHS of Moncks Corner SNF entered into its CIA on November 27, 2007. Over the course of its CIA, its pressure ulcer QMs improved by 8 percentage points (improving on average from 12% to 4% and exceeding threshold goals). The IHS of Moncks Corner CIA contained the following unique language related to pressure ulcers:

> Ensure that IHS provides appropriate wound care (decubitus ulcer) treatment and appropriate nutrition for residents with wounds.

An explanation for the improvement in pressure ulcer QMs for these two SNFs is likely partially attributable to that specific language included in the CIAs which focused the Quality Monitor on the AHRQ clinical practice guidelines (including the detailed self-monitoring that the AHRQ guidelines require as per **Chapter 2, Figure 2-2**) in the Green Acres case, and on the importance of focusing on nutrition and wound care in the IHS case.

These results from Research Objective Three inform the specific recommendations of how CIA documents should be improved. Specifically, CIA

documents should include specific requirements related to: (1) which evidence-based guidelines should be followed for specific SNF quality problems, (2) details about the type and frequency of self-monitoring that a SNF should perform (including a requirement for the SNF to assess its own QM data and track and trend), (3) details about the QM threshold ranges that a SNF should reach by various checkpoints in the CIA, (4) details about how the individual SNF should track data showing how the SNF compares to the national average and to other SNFs in the chain on key QMs for that SNF (and details about the systems required to spread positive change from one SNF to another within a SNF corporation), (5) recommendations about individual staff positions that the SNF needs to create given its quality problems (such as a wound care nurse), (6) details about how the SNF will staff to acuity including detailed requirements for weekly acuity assessment meetings, and finally (7) a requirement that the SNF Quality Monitor have unfettered access to the SNF's payroll data and to "all financial documentation which is relevant to resident care."

It is probable that the SNF industry, and even HHS-OIG who negotiates the CIA agreements, may push back and argue that this level of specificity runs counter to the 'spirit of the CIA' which is to be a collaborative quality improvement document between the government and a provider. However, this study shows that CIAs are not significantly improving SNF quality, and given the extensive federal government resources invested in obtaining and monitoring a CIA, a more effective CIA document is needed to achieve the federal government's goal of protecting vulnerable SNF residents from inadequate skilled nursing care.

2. Recommendations to Improve the 'During-CIA' Quality Monitoring Process.

Dr. David Zimmerman, who is currently a CIA Quality Monitor, was instrumental in the late 1990's in developing the CIA contract and the quality monitoring process in consultation with HHS-OIG. Dr. Zimmerman maintains that "the most important goal of the CIA monitoring process is to instill the ability and the will in the SNF corporation to do the same type of self-monitoring that the CIA Quality Monitor had done for 5 years and to leave the SNF in a position to be able to self-monitor well after the CIA Quality Monitor has left."[106] Dr. Zimmerman believes that it is critical that the SNF engage in the care self-validation process just as the Quality Monitor would, meaning that "if the medical record states that the CNA turned and repositioned the resident every two hours, the SNF must be able to validate and verify that this in fact occurred." *Id.*

This study showed that there was not significant improvement, and in the case of pressure ulcers, there was QM worsening during the CIA process. Therefore, changes need to be made to the CIA quality monitoring process in several general areas: assessing and, in some cases, changing SNF leadership, following evidence-based protocols, doing root cause analyses, teaching tracking and trending, assessing acuity, and ensuring staffing to acuity.

Specifically, during the CIA monitoring process, Quality Monitors should be required by HHS-OIG to regularly do the following: (1) the Quality Monitor should assess SNF leadership (in particular the Medical Director and the Director of Nursing) and clinical staff to ensure that the leadership and clinical staff support a culture of quality. One of the primary characteristics that make a SNF amenable to quality

[106] Telephone interview with Dr. David Zimmerman (December 30, 2015).

improvement is the presence of senior leadership who are committed to a culture of quality within the organization. (Rantz, et al., 2012); (2) the Quality Monitor should ensure that the SNF clinical staff is trained in and able to use evidence-based protocols related to the specific quality issues that the SNF faces. One of the key reasons that clinical staff do not use evidence-based protocols is lack of training. (Berlowitz, et al., 2003, Colon-Emeric, et al., 2007); (3) the Monitor should work with the SNF to develop its own process of root cause analysis so that the SNF can identify the reasons for care failures and not simply engage in a process of crisis management; (4) the Monitor should see that the RN, LPN, and CNAs are trained in tracking and trending and that the nursing staff is capable of tracking the QM data to be provided to the SNF's own Quality Assurance Committee on a regular basis (Horn, et al., 2010) (this would include assisting the SNF to set reasonable threshold ranges for QM improvement over the course of the CIA);[107] (5) the Monitor should assess the quality of all professionals with whom the SNF contracts to ensure that, for example, the wound care clinicians and therapists are all providing quality care; (6) the Monitor should ensure that the SNF performs accurate and effective care planning, including discharge planning for all residents with involvement of the facility's interdisciplinary team (Levinson, *OIG Report*, November 2012); (7) the Monitor should ensure that SNF staff is properly trained on caring for residents with dementia and in preventing elder abuse; (8) the Monitor should ensure that the SNF has a sound infection prevention and control program; (9) the Monitor should require that the

[107] The scientific literature support that the use of data capture and analysis can improve pressure ulcer QMs. The following three protocols were successful in reducing pressure ulcers from 13% to 8.7% in 12 months (Horn et al., 2010): (1) establish a standardized set of comprehensive documentation and data elements and definitions across facilities; (2) address DON and staff turnover effects in implementation planning; and (3) use health information technology to capture reports and documentation.

SNF hold bi-weekly acuity meetings to assess facility acuity on an on-going basis; the Monitor can then check and refine the SNF's acuity assessment process; and (10) finally, the Monitor should work closely with the facility to discuss a specific method to develop a staffing plan so that the facility can consistently staff to acuity.

In the event that the SNF does not follow the direction of the Quality Monitor and fails to adhere to the requirements of the CIA, the CIA document provides for remedies during the CIA period if the SNF breaches the CIA requirements. There are basically two remedies during the CIA period that should be used if the SNF breaches the CIA agreement: (1) stipulated penalties (stipulated penalties were discussed in detail in **Chapter 2 Section B)** and (2) exclusion for material breach of the CIA. While HHS-OIG rarely excludes a provider for breach of a CIA, in April 2014, HHS-OIG entered into a five-year exclusion agreement with Church Street Health Management (a pediatric dental chain investigated for performing unnecessary pediatric root canals) for repeated material breaches of the CIA.[108]

3. Recommendations to Develop a Post-CIA Follow-up Program.

This study found that there was not significant improvement, and in the case of pressure ulcers, there was QM worsening in the post-CIA process. Currently, there is no process in place to follow-up with a SNF corporation or SNF facility after the conclusion of its CIA. The day that a CIA ends is the last interaction that the SNF has with the monitoring process other than the unrelated state surveys which all SNFs are subject to. During the CIA period, many SNFs are required to adopt care processes that are costly and that are known to improve quality, i.e., hiring additional or new staff, engaging in

[108] May, M., et al., "CIAs" *Law360*, New York (May 27, 2014).

root cause analyses, and tracking and trending performance. There is a significant concern that was in large part borne out by this study's results, that once the CIA ends, the SNF will change its quality culture and revert back to its pre-CIA *modus operandi*. In fact, CMS' Special Focus Facility Program found that once a SNF graduated from the SFF program, relapse on surveys and obtaining survey deficiencies was common (2013 CMS SFF Study).

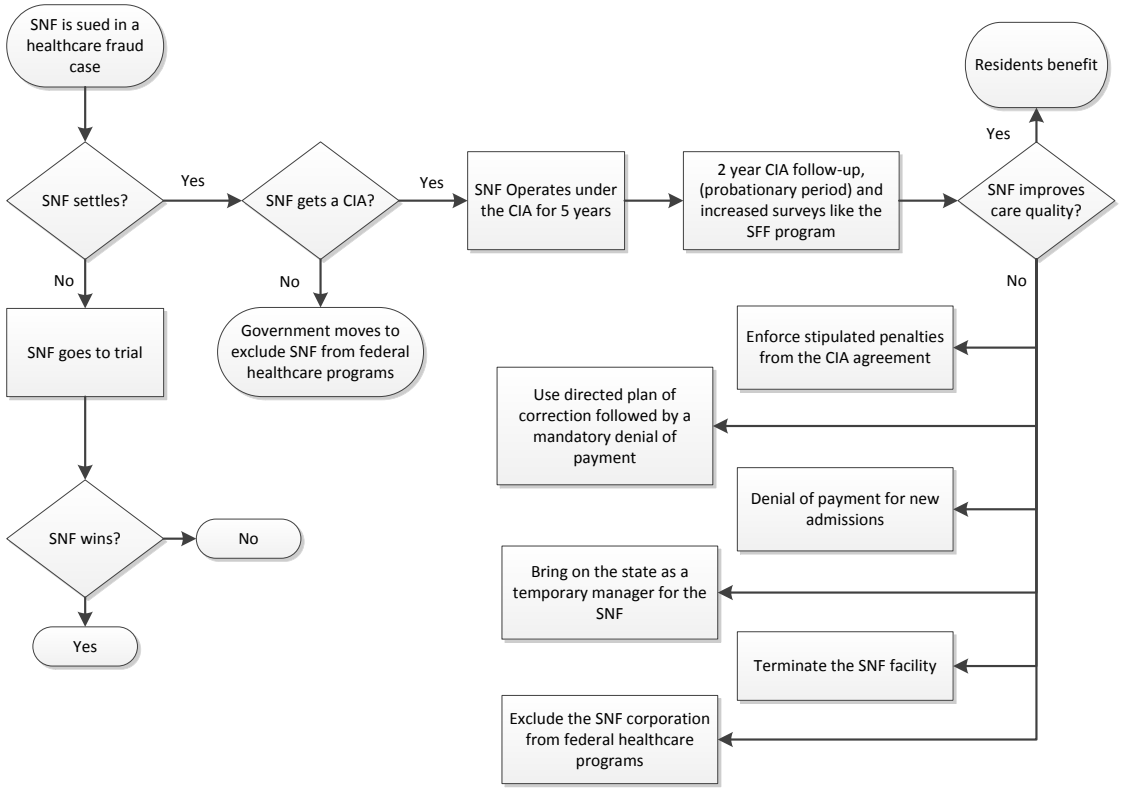
Given that the federal government relies on CIAs as one of its key quality improvement tools, given that the federal government expends considerable resources on federal healthcare fraud prosecutions and the CIA negotiation process, and given that poor quality of care in SNFs means vulnerable residents suffer, it is critical that the federal government continue to monitor SNFs that have completed quality CIAs for at least two years post-CIA and that the government use all of the enforcement tools at its disposal to ensure that CIA SNFs maintain or obtain quality improvements post-CIA.

Recent nursing home studies show that regulatory stringency is significantly associated with higher quality on multiple measures, supporting the value of strong regulatory oversight. (Harrington, et al. 2014). Harrington, et al., found that unless CMS and state survey agencies develop stronger sanctions and enforcement procedures that focus on chains with quality problems, it is unlikely that large chains will comply with quality requirements. *Id.*

Figure 5-1 below shows the Workflow Diagram of how a SNF becomes subject to a CIA (this process was described in detail in **Chapter 1**) and informs my proposal for the development of a two-year post-CIA follow-up process. This Workflow Diagram further depicts my policy recommendations for post-CIA regulatory follow-up based on

the current tools that the federal government (through both HHS-OIG and CMS) has to ensure improved SNF quality post-CIA.

Figure 5-1 – Workflow of Recommendations to Improve the Post-CIA Follow-up Process



Once a SNF has completed its CIA, I propose that the SNF enter a two-year probationary period where the SNF would be subjected to increased state surveys exactly as required by CMS' Special Focus Facility (SFF) Program. Under the SFF Program, once a SNF has been designated as a SFF, the SNF is subjected to surveys every six months and the penalties for poor surveys results increase. During this proposed two-year post-CIA period, surveyors could document quality problems that would inform the possible use of the other enforcement tools described below.

As depicted in **Figure 5-1**, once a SNF completes its two-year probationary period, if quality is still a problem, then the federal government should begin to use a graduated series of enforcement tools and penalties to bring the SNF corporation or

facility into quality compliance. The first level of enforcement that HHS-OIG could use is to enforce the stipulated penalties that are enumerated in the CIA agreement.[109] The second level of enforcement action that CMS could take post-CIA is to require the SNF to develop several plans of correction to improve the care areas where the SNF has problems, and if these plans of correction do not result in improved quality in a three-month timeframe, then CMS could impose a mandatory denial of Medicare payments on the SNF. A third level of enforcement action that CMS could take if the quality of care in the SNF fails to improve is a denial of Medicare payments for new resident admissions.

In the event that the quality of care in the post-CIA SNF remains significantly problematic, CMS and/or DOJ could move to have a temporary receiver or the relevant state run the SNF. Further, CMS could terminate the SNF. And finally, if the quality of care in a SNF that is part of a chain is extremely problematic, HHS-OIG could move to exclude the entire chain from participation in federal healthcare programs. For most SNF providers, the specter of exclusion, and avoiding exclusion, is the very reason that SNFs seek to settle with the federal government and agree to be bound by a CIA.

Some may argue that given that a CIA is an agreement that a SNF voluntarily enters into as part of a healthcare fraud settlement, if a SNF were subject to this two-year probationary period, SNF management might not agree to enter into what would effectively be a seven year CIA. The truth of the matter is that if the SNF is faced with a choice of exclusion or a lengthy CIA, I hypothesize that most SNFs would choose a CIA even with the additional two year post-CIA monitoring period.

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[109] If the HHS-OIG had evidence of breach during the CIA period, HHS-OIG could also have enforced the stipulated penalties during the CIA term as well.

4. Recommendation for a Federal Mandatory Minimum Staffing Level.

As discussed in **Chapter 2, Section L** there is strong support in the literature, beginning with the 2002 CMS Report to Congress, for a federal mandatory minimum staffing level. In that report, CMS stated that it found "strong and compelling statistical evidence" that SNFs with a low ratio of nursing staff to residents were more likely to provide substandard care and recommended a minimum staffing level of 4.1 hours of care per resident day.[110] CMS' analysis identified staffing thresholds that maximize quality outcomes and concluded "quality is improved with incremental increases in [total] staffing up to the identified [4.1 hours per resident day] threshold." *Id.* The CMS minimum nurse staffing threshold was confirmed by Schnelle et al., in 2004.

The literature and the experts agree that inadequate staffing is associated with lower QMs and poor care quality.[111] This is particularly true today when the SNF population includes such a medically complex and diverse resident population as - the 85 year old frail resident with pneumonia and the broken hip, as well as - the 55 year old resident who just had bypass surgery and had instability and a foot wound. SNFs today are caring for the long-term residents who need one level of care and the short-term residents who many times need more intensive acute care.

[110] CMS "Appropriateness of Minimum Staffing Ratios in Nursing Homes," Report to Congress. Baltimore: Centers for Medicare and Medicaid Services. (2002).
[111] Telephone interview with Dr. Sue Renz (December 28, 2015), and telephone interview with Dr. David Zimmerman (December 30, 2015).

As shown in the **Figure 5-2** and **Figure 5-3** Skilled Care Workflow Diagrams below, there are two distinct care models and staffing required for long-term skilled care and short-term skilled care residents in a SNF.

Figure 5-2 – Skilled Care Long Term Workflow Diagram[112]

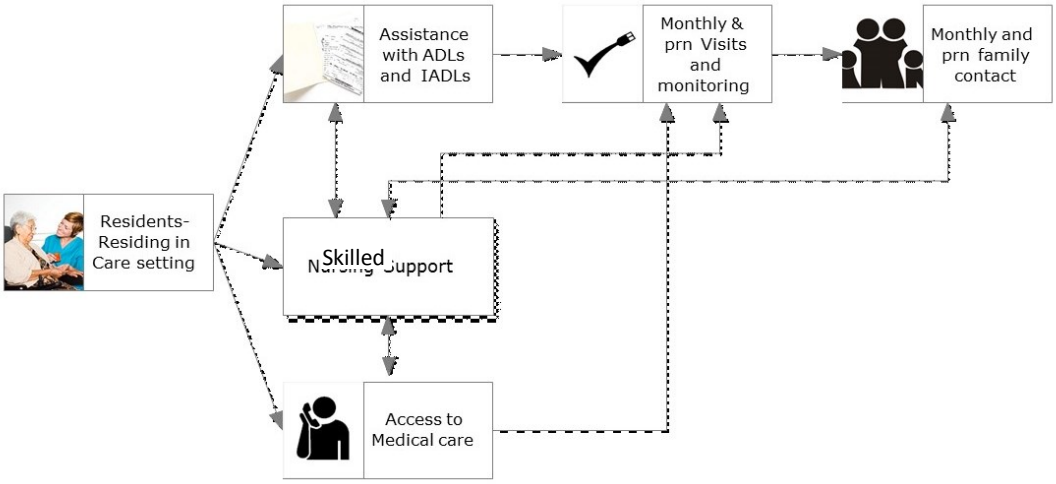
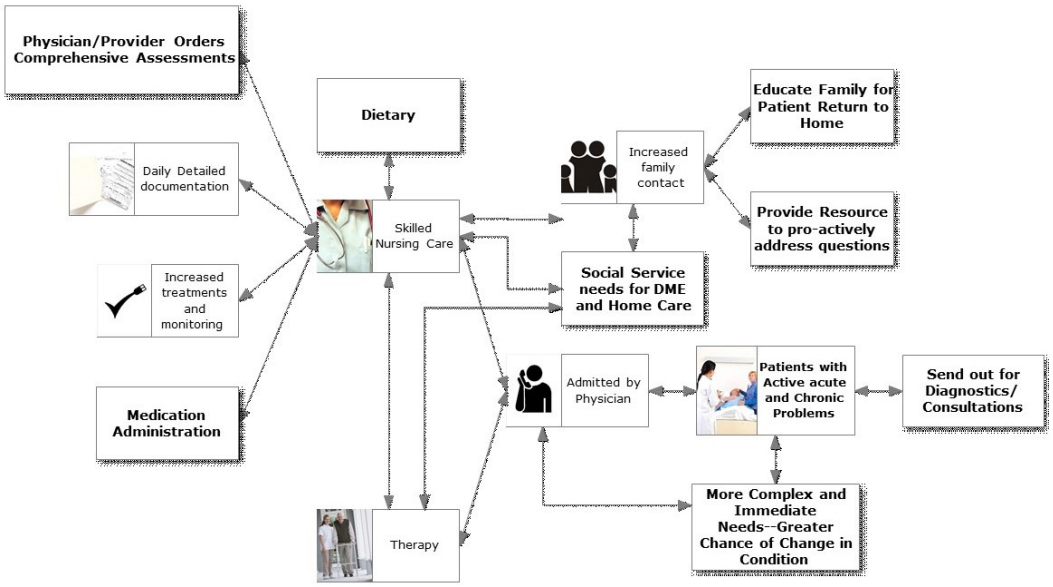


Figure 5-3 – Skilled Care Short Term Workflow Diagram



[112] These skilled care workflow diagrams were adapted from models used in healthcare fraud prosecutions.

Given these two different and challenging populations and care models at work in SNFs today, it is critical that SNFs have a baseline level of staffing to meet their residents' diverse care needs. Each facility must staff at a minimum level in order to care for the different needs of these diverse populations or the short-term residents will not get the complex sub-acute care that they need and the long-term residents will be ignored while the available staff triage the sub-acute cases. It is for this reason, and based on the results of my national threshold-driven staffing analysis, that I recommend a federal mandatory minimum of 4.0 HPRD for SNFs receiving Medicare and Medicaid reimbursement.

C. Study Strengths and Limitations.

This research study has a number of significant strengths. First, the longitudinal nature of this study over the 2003 to 2015 timeframe controlled for SNF variable characteristics which allowed me to isolate changes in SNF quality related to quality CIAs. Second, this study had sufficient sample size to permit me to stratify the sample by SNF structural factors, staffing, and acuity, in order to fully examine secondary effects that influence CIA impact on SNF quality.

Third, this study controlled for unrelated national SNF quality trends which could have influenced CIA effect on quality. Fourth, the outcome measures used in this study included two QMs that were supported in the literature as good indicators of SNF quality (Hillmer, et al., 2005, Palmer, 2008, Burfield, et al., 2012, Bell, et al., 2013, Arling, et al., 2007), and as reliable and valid (Mor, et al., 2011, Zhang, et al., 2009, Sangl, et al., 2005, Kash, et al., 2009). Fifth, the results of this study are highly generalizable to other SNFs in the United States because this study used the entire SNF population.

Finally, this study focused on the critical policy question of whether CIAs are effective in improving SNF quality of care for some of this nation's poorest-performing SNFs, and addressed some important, related SNF staffing issues.

This study also has limitations. First, the NHC MDS and QM data used in this study are self-reported by the SNFs which could subject these data to inaccuracy, variation or detection bias. It is possible that some of the observed QM improvements or worsening effects reflect changes in data-reporting practices rather than actual improvements in care (Zinn, et al., 2005). The threat to internal validity as a result of detection bias could be due to differences in the ability of clinical staff to detect residents' status and symptoms particularly in clinical areas that are harder to define such as early-stage pressure ulcers (Zinn, et al., 2005, Mor, et al., 2003). Further, other researchers have maintained that the facility-level data used to indicate the quality outcomes of residents is not the most accurate assessment of resident care (Zhang et al., 2006).

A second limitation is that researchers have found that NHC QM data have many blank data fields (Castle, et al., 2007). In large part because NHC does not report values for SNFs with fewer than 30 residents in the denominator for that SNF's QMs, there is some missing data in the analysis.

A third limitation is that, during the twelve-year period of this longitudinal study, CMS updated the MDS 2.0 to MDS 3.0. This update resulted in a two-quarter gap in data between Q4 2010 and Q1 2011, and in a slight re-definition of the pressure ulcer QM in this study which could theoretically have led to an instrumentation bias and a skewing of the results. However, as discussed in detail in **Chapter 4**, because the MDS 2.0 and

MDS 3.0 data were accounted for in my statistical model, the results of this study were not skewed by this instrumentation change.

Fourth, while I have used two QMs in this study that are considered strong indicators of SNF quality, there is not one universal, operational definition of what constitutes quality in SNFs, and some could argue that other QMs should have been used (as discussed in this Chapter in **Section D, Implications for Future Research**). For example, some researchers maintain that other QMs are also strong indicators of SNF quality: ADL worsening, pain, incontinence, bedfast status, worsening in mobility, urinary tract infection, increase in depression, use of physical restraints, and unexpected weight loss (Grabowski, et al., 2014). Other researchers maintain that a global or composite indicator of SNF quality is appropriate (Castle et al., 2011).

A fifth related limitation is that, while nursing home quality is a multidimensional construct with a wide array of quality measures (Castle, et al., 2007), this study only included a small subset of those measures. Therefore, SNFs could have had increasing or decreasing quality in many areas and this would not have been reflected in their pressure ulcer or catheter use QM scores.

A sixth limitation of this study is that while nurse staff turnover and use of agency staff have a significant association with low SNF quality (Bostick, et al., 2006, Zimmerman, S., et al., 2002) these factors could not be studied here because CMS did not require submission of these data for much of the study period. Studies have shown that an analysis of the effect of staffing on SNF resident outcomes should include an analysis of staff turnover rates and agency staff use (Grabowski et al., 2007). Because some of

these data were not available for my study period, only staffing level and staffing mix were examined.

A seventh limitation of this study is that the results could be vulnerable to regression to the mean for the two QM scores, because CIA SNFs are typically among the lowest-performing SNFs in the country. And a final limitation of this study is that the study could be vulnerable to threats to internal validity from external events other than CIA impact during this timeframe. Other CMS or state-based quality improvement initiatives or existing compliance programs in the individual SNFs, other than the quality CIAs, could have contributed to the slight improvement in QM scores seen in catheter use, for example.

In sum, this is the first study to investigate and validate the significance of CIA impact on SNF quality of care, investigate and validate the influence of SNF structural factors, staffing levels, and SNF resident case-mix acuity on CIA impact, as well as to examine the significance of any differences between national SNF QM averages and CIA-covered SNF QM averages. The results show that changes in the CIA document, CIA monitoring process, and post-CIA follow-up process are necessary to maximize the effect that CIAs could have on SNF care quality.

D. Implications for Future Research.

This study raised several methodological and theoretical issues that future research could address. First, this study assessed the effectiveness of a CIA on SNF quality of care by examining two dependent variables: the percent of long-stay residents with pressure ulcers and the percent of long-stay residents who have had an indwelling catheter. Future research could examine the effect of a CIA on SNF quality by

expanding this set of dependent variables to include other critical SNF quality measures such as falls, unintended weight loss, antipsychotic use, pain control, and nutritional status (Hillmer, et al., 2005, Palmer, 2008, Burfield, et al., 2012, Bell, et al., 2013, Arling, et al., 2007). Future research could also examine multiple outcome measures. Kane, et al., concluded that there is consensus about the most relevant domains for long-term care quality which include: physiological (blood pressure, blood sugar, and skin condition); functional (ADLs); pain and discomfort; cognition; affect; social activities; social relationships; and satisfaction with the care setting (Kane, et al., 1998). These domains are all captured in the MDS data. Finally, future research could examine the effect of a CIA on SNF quality by including an examination of SNF deficiencies. (Zimmerman, 2003).[113]

Second, future research could engage in a more nuanced SNF staffing analysis using the staffing payroll data that CMS will soon have access to pursuant to the Improving Post-Acute Care Transformation (IMPACT) Act of 2014. The IMPACT Act requires that, by 2016, SNFs report staffing levels, staffing mix, and staffing turnover data based on payroll records that will be auditable as opposed to self-reported (Dellefield, et al., 2015). A more nuanced staffing analysis could study nursing staff turnover as an additional covariate and could break out the staffing levels and analyze these levels individually according to HPRDs of RNs, LPNs, and CNAs. A future study could also consider the number of therapy staff (occupational, speech, and physical)

[113] Health deficiency count data is recorded in the Nursing Home Compare (NHC) website and is based on state inspections for Health Safety. CMS contracts with the states to survey SNFs at first when they are certified by Medicare and Medicaid and again every 9 to 15 months. When surveyors determine that an area of SNF care does not meet Federal standards, they issue a "deficiency tag." The deficiency tag refers to the number of affected residents and to the severity of the harm. A future study could use the deficiencies each year for SNFs that have a scope and severity of D or higher (because severity levels A thru C are considered to be in substantial compliance (HHS-OIG Report, April 2009)).

working with or at the SNF in the analysis. A future study could also examine different types of interactions among staff to examine associations with quality, for example, analyzing the effect of the use of more temporary RN staff on quality (Castle, et al., 2007). Finally, a future staffing study could examine the impact of staffing at different levels of quality, meaning does additional staff impact quality differently depending on the level of SNF quality starting at the baseline (Arling, et al., 2007).

Third, future research could use a more refined or multifaceted measure of acuity.[114] The resident acuity measures used in this study were ADL-driven, and if there are unmeasured differences in case-mix acuity across the SNFs that are correlated with the outcomes studied, this could potentially have biased the study results. Finally, future studies could do an in-depth analysis of the effect of SNF conversion (from for-profit to not-for-profit and from not-for-profit to for-profit) during the pendency of a CIA on SNF quality measures.

[114] As discussed in detail in **Chapter 3**, I calculated aggregated SNF-level resident case-mix acuity using OSCAR/CASPER data and average scores for dependency on activities of daily living (ADLs) for each SNF at the facility level. This method of calculating aggregated SNF resident case-mix acuity has been relied on in several scientific studies (Grabowski, 2004, Harrington, et al., 2003).

APPENDIX A – CIA Table

Appendix A - Corporate Integrity Agreement Table

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
1	VENCOR, INC./ KINDRED Vencor was renamed Kindred after 2001.	4/20/2001 to 1/1/2008	167	Yes	AL AZ CA CO CT GA ID IN KY MA ME MO MT NC NH NV OH OR PA RI TN TX UT VA VT WA WI WY	**Previous compliance program:** Vencor operated a Compliance Program prior to its CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Vencor was required to implement policies and procedures that ensured that residents and patients were discharged only for the reasons authorized by and in accordance with the procedures established by applicable law and not discharged for financial reasons unless authorized by law; that ensured staffing needs are decided first and foremost upon achieving the level of care for Vencor's residents required by Federal health care program requirements and state laws.	$104,500,000.00

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
2	NATIONAL HEALTHCARE CORPORATION – JOPLIN	12/12/2001 to 9/18/2006	1	Single facility	MO		$250,000.00
3	SUN HEALTHCARE GROUP, INC.	2/28/2002 to 8/22/2007	201	Yes	AL AZ CA CO CT FL GA ID IL IN LA MA MD NC NH NJ NM OH TN TX VA WA WV		

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
4	MARINER HEALTH CARE, INC.	4/3/2002 to 9/7/2007	273	Yes	AL AZ CA CO CT FL GA IL LA MA MD MI MS NC NE OH PA SC TN TX VA WI WV WY	**Previous compliance program:** Mariner had established a Compliance Program prior to its CIA and agreed to maintain its Compliance Program for the duration of its CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Mariner was required to implement policies that ensured that staffing needs were decided first and foremost upon achieving the level of care for Mariner's residents required by Federal and state laws; to minimize the use of temporary staff; to ensure the completion of accurate clinical assessments; to ensure that cost reports were accurate; and that there were no perverse financial incentives that would lead to poor quality outcomes.	
5	SUBURBAN WOODS, LLC.	7/12/2002 to 11/8/2005	1	Single facility	PA		$1,805,900.00
6	WOODBINE HEALTHCARE AND REHABILITATION CENTRE	12/13/2002 to 10/16/2006	1	Single facility	VA		$25,000.00

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
7	AMERICAN HEALTHCARE, L.L.C.	8/1/2003 to 12/16/2008	10	Yes	VA		$1,250,000.00
8	MARY J. DREXEL HOME	8/21/2003 to 3/1/2007	1	Single facility	PA		$875,000.00
9	MAJESTIC OAKS NURSING HOME	6/29/2004 to 4/2/2008	1	Single facility	PA		$50,000.00
10	HARBOR HEALTHCARE AND REHABILITATION CENTER	10/28/2005 to 2/12/2009	1	Single facility	DE	**Previous compliance program:** None. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Harbor was required to minimize the number of temporary staff; to ensure that residents with dementia are provided daily structured activities; and to ensure compliance with state staffing requirements.	$150,000.00

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
11	LIFE CARE CENTER OF LAWRENCEVILLE	12/20/2005 to 3/3/2011	1	Single facility	GA	**Previous compliance program:** Lawrenceville had established a clinical quality assurance program called the Performance Improvement Committee. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Lawrenceville was required to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; and to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
12	PLUM GROVE PALATINE, LLC	5/4/2006 to 7/15/2009	1	Single facility	IL	**Previous compliance program:** None. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Plum Grove was required to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Plum Grove had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
13	ATHENA HEALTH CARE ASSOCIATES, INC.	7/10/2006 to 1/6/2012	2	Single facility	CT	**Previous compliance program:** None. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Athena was required to ensure that Athena Facilities had systems in place to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Athena had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	
14	LOCHEARN NURSING HOME, LLC	8/4/2006 to 11/3/2009	1	Single facility	MD		
15	BRIGHTEN AT BROOMALL	2/14/2007 to 7/15/2010	1	Single facility	PA		$45,000.00

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
16	CIENA HEALTHCARE MANAGEMENT, INC.	8/2/2007 to 12/5/2012	23	Yes	MI	**Previous compliance program:** None. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Ciena was required to ensure that Ciena Facilities had systems in place to complete accurate clinical assessments; to meet state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Ciena had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	$1,250,000.00

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
17	IHS/UNIHEALTH POST-ACUTE CARE OF MONCKS CORNER, INC.	11/27/2007 to 7/20/2009	1	Single facility	SC	**Previous compliance program:** None. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** IHS was required to ensure that IHS Facilities had systems in place to complete accurate clinical assessments; to meet state staffing requirements and federal regulatory physician requirements; to ensure the provision of nursing care with the accepted professional standards of care such as assessment, planning, implementing and evaluating long-term care residents; to minimize temporary staff; to ensure that residents are not inappropriately discharged; and to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
18	A & C HEALTH CARE SERVICES, INC.	1/4/2008 to 10/26/2011	2	Yes	CA	**Previous compliance program:** A&C Healthcare Services purchased four SNFs subject to the Pleasant Care CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** A&C was required to ensure that A&C Facilities had systems in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that A&C had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
19	G & R ALAMEDA HEALTHCARE SERVICES, LLC	2/7/2008 to 6/16/2011	1	Single facility	CA	**Previous compliance program:** G&R Healthcare Services purchased one SNF subject to the Pleasant Care CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** G&R was required to ensure it had systems in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that G&R had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
20	COUNTRY VILLA NOVATO HEALTHCARE CENTER, LLC	2/7/2008 to 10/17/2011	1	Single facility	CA	**Previous compliance program:** Country Villa Novato purchased one SNF subject to the Pleasant Care CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Country Villa Novato was required to ensure that it a system in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Country Villa Novato had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
21	CORONA CARE CONVALESCENT CORPORATION	3/21/2008 to 10/26/2011	1	Single facility	CA	**Previous compliance program:** Corona Care purchased one SNF subject to the Pleasant Care CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Corona Care was required to have systems in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Corona Care had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
22	CORINTHIAN SUBACUTE HEALTHCARE CENTER, INC.	4/2/2008 to 7/22/2011	1	Single facility	CA	**Previous compliance program:** Corinthian purchased one SNF subject to the Pleasant Care CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Corinthian was required to ensure that it had systems in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Corinthian had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
23	NORWALK SKILLED NURSING & WELLNESS CENTRE, LLC	4/25/2008 to 10/17/2011	1	Single facility	CA	**Previous compliance program:** Norwalk purchased one SNF subject to the Pleasant Care CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Norwalk was required to ensure that it had systems in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Norwalk had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
24	INTEGRATED NURSING AND REHABILITATION CARE OF GLENDORA	5/19/2008 to 7/22/2011	1	Single facility	CA	**Previous compliance program:** Glendora purchased one SNF subject to the Pleasant Care CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Glendora was required to ensure that it had systems in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Glendora had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
25	INTEGRATED NURSING AND REHABILITATION OF PERRIS, INC.	6/23/2008 to 7/22/2011	1	Single facility	CA	**Previous compliance program:** Perris purchased one SNF subject to the Pleasant Care CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Perris was required to ensure that it had systems in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Perris had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
27	HIGHLAND PARK SKILLED NURSING & WELLNESS CENTRE	9/4/2008 to 3/12/2012	1	Single facility	CA	**Previous compliance program:** Highland Park purchased one SNF subject to the Pleasant Care CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Highland Park was required to ensure that it had a system in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Highland Park had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
28	COUNTRY VILLA PARK AVENUE HEALTHCARE CENTER, LLC	11/21/2008 to 4/2/2012	1	Single facility	CA	**Previous compliance program:** Country Villa Park Avenue purchased one SNF subject to the Pleasant Care CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Country Villa Park Avenue was required to ensure that it had a system in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Country Villa Park Avenue had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
30	EXTENDICARE	9/26/2014 to 9/25/2019	131	Yes	AL ID IN KY MI MN OH OR PA WA WI	**Previous compliance program:** Prior to its CIA, Extendicare established a voluntary corporate compliance program which included a Chief Compliance Officer, Code of Conduct, written policies and procedures, a disclosure program, screening measures, regular compliance training for employees, and various compliance auditing programs. **Specific Staffing requirements:** Extendicare was required to establish a Staffing Review Committee to assess the nursing staffing provided at Extendicare facilities and make recommendations regarding staffing. **Policy requirements and scope of Independent Monitor Review:** Extendicare was required to ensure that it had a system in place to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to ensure nursing staff levels are sufficient to meet residents' needs; to determine appropriate direct care nursing staff levels and allocation for each class of nursing staff (e.g., RNs, LPNs, CNAs) using a measurable, resident needs and acuity-based protocol; and the delivery, management, and oversight of rehabilitation therapy services.	$38,000,000.00

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
32	BEVERLY ENTERPRISES, INC.	2/3/2000 to 8/28/2008	425	Yes	AL AR AZ CA FL GA HI IL IN KS KY MA MD MI MN MO MS NC NE NJ OH PA SC SD TN VA WA WI WV	**Previous compliance program:** Beverly operated a compliance program prior to its CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** There are no unique policies or provisions in the initial Beverly CIA from 2000. However, in a 2003 Amendment to the Beverly CIA, Beverly was required to ensure that it had a system in place to complete accurate clinical assessments; to meet state staffing requirements and federal regulatory physician requirements; to ensure the provision of nursing care with the accepted professional standards of care such as assessment, planning, implementing and evaluating long- term care residents; to minimize temporary staff; to ensure that residents are not inappropriately discharged; and to effectively collect and analyze staffing data, including staff-to-resident ratio and staff turnover.	$170,000,000.00

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
33	TWIN OAKS NURSING HOME, INC.	10/29/2001 to 6/1/2007	1	Single facility	LA		$100,000.00
34	IHS/LTC-FUNDAMENTAL LONG TERM CARE HOLDINGS, INC.	9/9/2003 to 12/16/2009	62	Yes	FL MO NM NV PA SC TX	**Previous compliance program:** LTC Holdings, Inc. assumed responsibility for some of the IHS facilities; a November 2005 Amendment to the original 2003 IHS CIA correspondingly conferred the same IHS provisions to LTC. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** IHS was required to ensure that it had a system in place to complete accurate clinical assessments; to meet state staffing requirements and federal regulatory physician requirements; to ensure the provision of nursing care with the accepted professional standards of care such as assessment, planning, implementing and evaluating long term care residents; to minimize temporary staff; and to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover.	
35	IHS/EXCEPTIONAL CARE, LLC	9/9/2003 to 9/27/2013	1	Single facility	IL		
38	IHS/THCI, INC.	11/22/2005 to 7/7/2009	4	Yes	OH PA		

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
40	GREEN ACRES	5/1/2007 to 9/16/2011	5	Yes	DE MD PA	**Previous compliance program:** Green Acres represented that it operated a compliance program. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Green Acres was required to ensure that it had a system in place to complete accurate clinical assessments; to meet state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Green Acres has a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, neglect, wounds that do not heal or are not treated properly, failure of dietary and nutrition services, failure to provide appropriate diabetic care, and failure to provide appropriate restorative care to residents. Green Acres' CIA made specific notice to include policies to address pressure ulcers and diabetes.	$143,000.00

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
41	LIFEHOUSE HEALTH SERVICES, LLC	10/30/2007 to 1/20/2011	5	Yes	CA	**Previous compliance program:** Lifehouse purchased several SNFs subject to the Pleasant Care CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Lifehouse was required to ensure that it had systems in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Lifehouse had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
42	INFINITY GROUP	1/2/200 to 4/29/2011	3	Yes	CA	**Previous compliance program:** Infinity Group purchased three SNFs subject to the Pleasant Care CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Infinity Group was required to ensure that it had systems in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Infinity Group had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
43	NAZARETH ENTERPRISES, INC.	2/7/2008 to 7/13/2011	2	Yes	CA	**Previous compliance program:** Nazareth Enterprises purchased two SNFs subject to the Pleasant Care CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Nazareth was required to ensure that it had a system in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Nazareth has a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
44	PETALUMA SKILLED NURSING & WELLNESS CENTRE, LLC	2/7/2008 to 10/17/2011	1	Single facility	CA	**Previous compliance program:** Petaluma purchased one SNF subject to the Pleasant Care CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** The Petaluma CIA was essentially limited to the preamble, introductory framing language, and minimal provisions. Most of the components were incorporated by reference through the original Pleasant Care CIA. Through reference to the Pleasant Care CIA, Petaluma was required to ensure that it had a system in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Petaluma had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
45	ISOCARE SNF, INC.	3/14/2008 to 3/12/2012	1	Single facility	CA	**Previous compliance program:** Isocare purchased one SNF subject to the Pleasant Care CIA. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Isocare was required to ensure that it had a system in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Isocare had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
46	CATHEDRAL ROCK	1/6/2010 to 11/16/2012	4	No covers a subset of the chain	IL MO	**Previous compliance program:** None. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Cathedral Rock was required to ensure that it had a system in place to complete accurate clinical assessments; to meet state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Cathedral Rock had a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	$628,000.00

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
47	FOUNDATION HEALTH SERVICES, INC	6/6/2014 to 6/6/2019	10	Yes	LA MD MS PA VA	**Previous compliance program:** None. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** Foundation was required to ensure that it had a system in place to complete accurate clinical assessments; to meet state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to effectively collect and analyze staffing data; and capital improvements, to ensure that Foundation and its nursing facilities address facility maintenance and repairs, equipment adequacy, supplies, and make necessary capital expenditures to provide a habitable environment.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
48	GGNSC HOLDINGS LLC	12/21/2012 to 12/21/2017	7	No covers a subset of the chain	GA MN WI	**Previous compliance program:** GGNSC had "maintained a voluntary compliance program for many years." **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** GGNSC was required to ensure that it had a system in place to complete accurate clinical assessments; to meet state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to effectively collect and analyze staffing data. The GGNSC CIA addressed pressure ulcer and wound care in significant detail, including training, adequate skin care, nutrition, hydration, turning and the use of turning schedules (with a maximum of every two hours for non-ambulatory residents), positioning, application of pressure reduction or relief devices; and clean and dry bed linens, assessment upon admission and RN assessment and documentation, use of color photographs for all Stage III and Stage IV pressure ulcers, and prompt communication with the resident's family member or legal representative, and with the resident's treating physician, of new skin tears, bruises, and pressure ulcers and of the improvement or worsening over time.	

CIA #	Corporate Entity/Provider name	CIA Start and End Dates	# SNFs Under CIA	Full Chain CIA or no	States with covered SNFs	Unique CIA Provisions, included among standard quality CIA language, if any	Federal Healthcare Settlement Amount
50	PLEASANT CARE	3/6/2006 To 3/6/2011	3	Covers a subset of the chain.		**Previous compliance program:** None. **Specific Staffing requirements:** None. **Policy requirements and scope of Independent Monitor Review:** This Pleasant Care CIA was copied or referenced in several other successor CIA documents when the Pleasant Care SNFs were sold off. SNFs that were sold off were captured under the successor CIA, not this original Pleasant Care CIA. Pleasant Care was required to ensure that it had systems in place to complete accurate clinical assessments; to meet California state staffing requirements; to minimize temporary staff, to ensure a coordinated interdisciplinary approach to providing care; to have effective protocols designed to prevent falls, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans; to effectively collect and analyze staffing data, including staff-to-resident ratio, staff turnover, and staffing during the periods in which falls occurred; and to ensure that Pleasant Care has a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect.	

APPENDIX B – Extendicare CIA

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
EXTENDICARE HEALTH SERVICES, INC.
AND
THE PROGRESSIVE STEP CORPORATION

I. PREAMBLE

Extendicare Health Services, Inc. ("EHSI"), and The Progressive Step Corporation ("ProStep") (hereafter collectively referred to as "Extendicare") hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Extendicare is entering into a Settlement Agreement with the United States.

Prior to the Effective Date of this CIA (as defined below), Extendicare established a voluntary corporate compliance program (the Compliance Program). Extendicare's Compliance Program includes a Chief Compliance Officer, Code of Conduct, written policies and procedures, a disclosure program, screening measures, regular compliance training for employees, and various compliance auditing programs. Extendicare's Canadian parent company, Extendicare, Inc., has a Board of Directors Quality and Compliance Committee. Extendicare shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Extendicare may modify its Compliance Program as appropriate, but, at a minimum, Extendicare shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Extendicare under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA

executes this CIA, unless otherwise specified. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. This CIA applies to any long term care facility in which Extendicare has an ownership or control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), any long term care facility managed by Extendicare, and any Extendicare-owned supplier of rehabilitation therapy services to long-term care facilities. This CIA shall apply only to U.S. operations of Extendicare that are subject to U.S. Federal health care program requirements.

C. Sections VII, X, and XI shall expire no later than 120 days after OIG=s receipt of: (1) Extendicare's final annual report; or (2) any additional materials submitted by Extendicare pursuant to OIG=s request, whichever is later.

D. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

a. all owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), officers, directors, and employees of Extendicare;

b. all owners, officers, directors, and employees of any corporation, subsidiary, affiliate, joint venture, or other organization or entity in which Extendicare, or its individual owners, own 5% or more or have a controlling interest at any time during the term of the CIA, and that operates or supplies rehabilitation services to a long term care facility. This shall include any long term care facility that Extendicare or its individual owners have a management contract or arrangement to provide management and/or administrative services that give any of them control over the day-to-day operations of the organization or entity at any time during the term of the CIA; and

c. all contractors, subcontractors, agents, and other persons who: (1) are involved directly or indirectly in

the delivery of resident care; (2) make assessments of residents that affect treatment decisions or reimbursement; (3) perform billing, coding, audit, or review functions; (4) make decisions or provide oversight about staffing, resident care, reimbursement, policies and procedures, or this CIA; or (5) perform any other function that relates to or is covered by this CIA.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

Any nonemployee private caregivers and/or attending physicians hired by any resident or the family or guardians of any resident of Extendicare are not Covered Persons, regardless of the hours worked per year at Extendicare.

2. "Relevant Covered Persons" includes all Covered Persons who: (1) are involved directly or indirectly in the delivery of resident care; (2) are involved directly or indirectly in the delivery of rehabilitation therapy; (3) make assessments of residents that affect treatment decisions or reimbursement; (4) perform billing, coding, audit, or review functions; (5) make decisions or provide oversight about staffing, resident care, reimbursement, policies and procedures, or this CIA; or (6) perform any function that relates to or is covered by this CIA

III. CORPORATE INTEGRITY OBLIGATIONS

Extendicare shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Responsibilities of Compliance Officer, Compliance Committee, Board of Directors, and Staffing Review Committee

1. *Compliance Officer*. Within 90 days after the Effective Date, Extendicare shall appoint a Covered Person to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA, Federal health care program requirements, and professionally recognized standards of care. The Compliance Officer shall also be responsible for

monitoring the day-to-day compliance activities engaged in by Extendicare and any reporting obligations created under this CIA. The Compliance Officer shall ensure that Extendicare adopts procedures and systems intended to identify and correct quality of care issues. The Compliance Officer must have sufficient compliance and quality assurance experience to effectively oversee the implementation of the requirements of this CIA. The Compliance Officer shall be a member of senior management of Extendicare, shall report directly to the Chief Executive Officer of Extendicare, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Extendicare, and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request. The Compliance Officer shall not be or be subordinate to the General Counsel, Chief Financial Officer, or Chief Operating Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervised legal counsel functions for Extendicare. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Extendicare shall report to OIG, in writing, any changes in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee*. Within 90 days after the Effective Date, Extendicare shall appoint a Quality Assurance Compliance Committee (hereinafter "Compliance Committee").

a. *General Responsibilities*. The purpose of this committee shall be to support the Compliance Officer in fulfilling his/her responsibilities (e.g., developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA, Federal health care program requirements, and professionally recognized standards of care; monitoring the day-to-day compliance activities engaged in by Extendicare; monitoring any reporting obligations created under this CIA; and ensuring that Extendicare is appropriately identifying and correcting quality of care issues). The Compliance Committee shall, at a minimum, include the Compliance Officer, the corporate Medical Director,

representatives from among senior personnel responsible for clinical operations and quality of care, human resources, operations, and any other appropriate officers or individuals necessary to thoroughly implement the requirements of this CIA. The Compliance Officer shall chair the Compliance Committee. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

The Compliance Committee shall meet, at a minimum, every month. For each scheduled Compliance Committee meeting, senior management of Extendicare shall report to the Compliance Committee, on the adequacy of care being provided by Extendicare, and senior representatives from Extendicare's facilities shall be chosen, on a rotating and random basis, to report to the Compliance Committee on the adequacy of care being provided at their facilities. Attendance at such committee meetings by such senior management may be via conference phone or video conferencing equipment although in person attendance is the desired and intended form of attendance.

Extendicare shall report to OIG, in writing, any changes in the composition of the Compliance Committee, any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after the change.

b. *Quality of Care Review Program*. The Compliance Committee shall ensure that, within 120 days after the Effective Date, Extendicare establishes and implements a program for performing internal quality audits and reviews (hereinafter "Quality of Care Review Program"). The Quality of Care Review Program shall be designed to determine:

i. whether the residents at Extendicare are receiving the quality of care and quality of life consistent with professionally recognized standards of care, 42 C.F.R. Part 483, and any other applicable federal and state statutes, regulations, and directives;

ii. whether Extendicare is effectively reviewing quality of care related incidents and completing root cause analyses;

iii. whether Extendicare's action plans in response to identified quality of care problems are appropriate, timely, implemented, and enforced; and

iv. whether Extendicare's nursing staff is of the quantity, quality, and composition necessary to consistently meet resident care needs.

c. *Quality of Care Dashboard*. The Compliance Committee, in consultation with the Monitor required under Section III.E. of this CIA, shall create and implement a "Quality of Care Dashboard" (Dashboard), which will function as a performance scorecard for Extendicare. Within 120 days after the Effective Date, the Compliance Committee shall: (1) identify and establish the overall quality improvement goals for Extendicare based on its assessment of Extendicare's quality of care risk areas; (2) identify and establish the quality indicators related to those goals that Extendicare will monitor through the Dashboard; and (3) establish performance metrics for each quality indicator. The Compliance Committee shall measure, analyze, and track the performance metrics for the quality indicators on a monthly basis, monitoring progress towards the quality improvement goals. At least semi-annually, the Compliance Committee shall review the quality indicators to determine if revisions are appropriate and shall make any necessary revisions based on such review.

3. *Board of Directors Committee*. Within 90 days after the Effective Date, Extendicare shall create a committee as part of its Board of Directors (hereinafter "Board of Directors Committee").

a. *General Responsibilities.* The purpose of the Board of Directors Committee shall be to review and provide oversight of matters related to Extendicare's compliance with the requirements set forth in this CIA, Federal health care program requirements, and professionally recognized standards of care. The Board of Directors Committee must include independent (i.e., non-executive) members. The individuals who serve on the Board of Directors Committee shall be readily available to the Compliance Officer and the Monitor required under this CIA to respond to any issues or questions that might arise. The Board of Directors Committee shall, at a minimum:

i. meet at least quarterly to review and oversee Extendicare's Compliance Program, including, but not limited to, the performance of the Compliance Officer and the Compliance Committee;

ii. review the adequacy of Extendicare's system of internal controls, quality assurance monitoring, and resident care;

iii. confirm that Extendicare's response to state, federal, internal, and external reports of quality of care issues is complete, thorough, and resolves the issue(s) identified;

iv. confirm that Extendicare adopts and implements policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA, Federal health care program requirements, and professionally recognized standards of care; and

v. monitor Extendicare's performance under to the Dashboard and ensure that Extendicare implements effective responses when potential

quality issues are indicated on the Dashboard or when quality indicators show that Extendicare is not meeting its established goals.

Extendicare shall report to OIG, in writing, any changes in the composition of the Board of Directors Committee, or any actions or changes that would affect the Board of Directors Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

b. *Board of Directors Committee Resolution*. For the Implementation Report required under Section V.A and for each Reporting Period of the CIA, the Board of Directors Committee shall adopt a resolution (consistent with the bylaws for adopting resolutions) summarizing the Board of Directors Committee's review and oversight of Extendicare's compliance with the requirements set forth in this CIA, Federal health care program requirements, and professionally recognized standards of care. Each individual member of the Board of Directors Committee shall sign a statement indicating that he or she agrees with the resolution. At a minimum, the resolution shall include the following language:

"The Board of Directors Committee has made a reasonable inquiry into the operations of Extendicare's Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. The Board of Directors Committee has also provided oversight on quality of care issues. Based on its inquiry and review, the Board of Directors Committee has concluded that, to the best of its knowledge, Extendicare has implemented an effective Compliance Program and Extendicare is in compliance with the requirements of the CIA, the Federal health care programs, and professionally recognized standards of care."

If the Board of Directors Committee is unable to provide such a conclusion in the resolution, the Board of Directors Committee shall include in the written

resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to ensure that Extendicare implements an effective Compliance Program.

4. *Staffing Review Committee.* Within 90 days after the Effective Date, Extendicare shall establish a Staffing Review Committee (hereinafter "Staffing Committee"). The purpose of this committee shall be to assess the nursing staffing provided at Extendicare facilities and make recommendations regarding staffing. The Staffing Committee shall include at least the Compliance Officer and the Vice President of Clinical Services, and shall regularly solicit input from employees at every level of the organization, including direct care nursing staff. The Staffing Committee shall meet at least monthly and shall:

a. review the development and implementation of the staffing-related policies and procedures required by Section III.B.2.f of the CIA.

b. assess on an on-going basis whether Extendicare is providing the quantity, quality, and composition of nursing staff necessary to meet resident needs at each of its facilities;

c. make recommendations as to how Extendicare can ensure the appropriate quantity, quality, and composition of nursing staff necessary to meet resident needs;

d. identify challenges related to the recruitment, retention, job satisfaction, and training of nursing staff at each of Extendicare's facilities;

e. make recommendations as to how Extendicare can address challenges related to the recruitment, retention, job satisfaction, and training of nursing staff; and

f. report quarterly to the Compliance Committee on the reviews, assessments, and recommendations set forth in this Section III.B.4 of this CIA.

Extendicare shall report to OIG, in writing, any changes in the composition of the Staffing Committee or any actions or changes that would affect the Staffing

Committee's ability to perform the duties necessary to meet the obligations in this CIA within 15 days after the change.

B. Written Standards

1. *Code of Conduct*. Within 90 days after the Effective Date, Extendicare shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Extendicare shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. Extendicare's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

b. Extendicare's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Extendicare's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

c. the requirement that all of Extendicare's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Extendicare, suspected violations of any Federal health care program requirements or of Extendicare's own Policies and Procedures;

d. the requirement that all of Extendicare's Covered Persons shall immediately report to the Compliance Officer, or other appropriate individual designated by Extendicare, credible allegations of resident harm and such report shall be complete, full, and honest;

e. the possible consequences to both Extendicare and Covered Persons of failure to comply with Federal health care program requirements and with Extendicare's own Policies and Procedures and the failure to report such noncompliance; and

f. the right of all individuals to use the Disclosure Program described in Section III.F, and Extendicare's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by Extendicare's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Extendicare shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures*. Within 90 days after the Effective Date, Extendicare shall implement written Policies and Procedures regarding the operation of Extendicare's compliance program, including the compliance program requirements outlined in this CIA, Extendicare's compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. the compliance program requirements outlined in this CIA;

b. the requirements applicable to Medicare's Prospective Payment System (PPS) for skilled nursing facilities, including, but not limited to: ensuring the accuracy of the clinical data required under the Minimum Data Set (MDS) as specified by the Resident Assessment Instrument User's Manual; ensuring that Extendicare is appropriately and accurately using the current Resource Utilization Groups (RUG) classification system; and ensuring the accuracy of billing and cost report preparation policies and procedures;

c. compliance with the completion of accurate clinical assessments as required by applicable Federal law,

which shall include: (1) that all resident care information be recorded in ink or permanent print; (2) that corrections shall only be made in accordance with accepted health information management standards; (3) that erasures shall not be allowable; and (4) that clinical records may not be rewritten or destroyed to hide or otherwise make a prior entry unreadable or inaccessible;

d. compliance with Titles XVIII, XIX, and XX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1, 1396-1396w-5, and 1397; and all regulations, directives, and guidelines promulgated pursuant to these statutes, including, but not limited to, 42 C.F.R. Parts 424 and 483, and any other state or local statutes, regulations, directives, or guidelines that address quality of care in nursing homes, as well as professionally recognized standards of health care;

e. the coordinated interdisciplinary approach to providing care, including but not limited to the following areas addressed in 42 C.F.R. § 483:

i. resident rights;
ii. admission, transfer, and discharge rights;
iii. resident behavior and facility practices;
iv. quality of life;
v. resident assessment;
vi. quality of care;
vii. nursing services;
viii. dietary services;
ix. physician services;
x. specialized rehabilitative services;
xi. dental services;
xii. pharmacy services;
xiii. infection control;
xiv. physical environment;
xv. administration; and
xvi. mental health services.

f. staffing, including, but not limited to:

i. ensuring nursing staff levels are sufficient to meet residents' needs, as required by Federal and state laws, including, but not limited to, 42 C.F.R. § 483.30 (nursing services);

ii. a measurable, resident needs and acuity-based protocol to determine appropriate direct care nursing staff levels and allocation for each class of nursing staff (*e.g.*, RNs, LPNs, CNAs);

iii. ensuring that Covered Persons are informed of the staffing requirements of Federal and state law, that staffing levels are a critical aspect of resident care, and that, if any person has a concern about the level of staffing, there are many avenues available to report such concerns, including, but not limited to, the Administrator, the Disclosure Program (as described in Section III.F of this CIA), or directly to the Compliance Officer or Monitor; and

iv. minimizing the number of individuals working on a temporary assignment or not employed by Extendicare (not including those persons who are included in the definition of Covered Persons) and measures designed to create and maintain a standardized system to track the number of individuals who fall within this category so that the number/proportion of or changing trends in such staff can be adequately identified by Extendicare or the Monitor.

g. delivery, management, and oversight of rehabilitation therapy services, including, but not limited to, the requirements that skilled rehabilitation therapy:

i. be pursuant to physician orders

ii. be pursuant to an individualized plan of care including documented therapeutic goals;

iii. be consistent with the nature and severity of the resident's individual illness or injury;

iv. comply with accepted standards of medical practice;

v. be reasonable in terms of duration and quantity;

vi. be reasonable and necessary to improve a resident's current condition, to maintain the resident's current condition, or to prevent or slow further deterioration of the resident's condition.

vii. include only services that 1) require the skills of qualified technical or professional health personnel such as physical therapists, occupational therapists, and speech-language pathologists; and 2) must be provided directly by or under the general supervision of these skilled rehabilitation personnel to assure the safety of the resident and to achieve the medically desired result; and

viii. include thorough and timely documentation sufficient to enable a reviewer to determine whether all the criteria above have been meet.

Within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures. The Policies and Procedures shall be available to OIG upon request.

At least annually (and more frequently, if appropriate), Extendicare shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures.

C. Training and Education

1. *General Training*. Within 120 days after the Effective Date, Extendicare shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Extendicare's:

a. CIA requirements; and

b. Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

For purposes of the General Training requirements, if Extendicare provided training on its Compliance Program that satisfies the requirements set forth in Section III.C.1 above, to Covered Persons within 90 days prior to the Effective Date, then OIG will credit that training for purposes of satisfying the applicable part of Extendicare's General Training obligations for the first Reporting Period of the CIA.

2. *Specific Training*. Within 120 days after the Effective Date, Extendicare shall initiate the provision of Specific Training to each Relevant Covered Person. Within the first Reporting Period, each Relevant Covered Person shall receive at least six hours of Specific Training pertinent to their responsibilities in addition to the General Training required above. This Specific Training shall include a discussion of:

a. policies, procedures, and other requirements applicable to the documentation of medical records;

b. the policies implemented pursuant to Section III.B.2 of this CIA, as appropriate for the job category of each Relevant Covered Person;

c. the coordinated interdisciplinary approach to providing care and related communication between disciplines;

d. the personal obligation of each individual involved in resident care to ensure that care is appropriate and meets professionally recognized standards of care;

e. examples of proper and improper care; and

f. reporting requirements and legal sanctions for violations of the Federal health care program requirements.

New Relevant Covered Persons shall begin receiving this training within 10 days after the start of their employment or contract (or becoming Relevant Covered Persons) or within 120 days after the Effective Date, whichever is later.

For purposes of satisfying the Specific Training described in this section, any Relevant Covered Person, as defined in Section II.C.2 who, during the 90 days prior to the Effective Date of this CIA, received training that meets the requirements for Specific Training shall be considered to have completed the Specific Training requirements in Section III.C.2.

After receiving the initial Specific Training described in this section, each Relevant Covered Person shall receive at least six hours of Specific Training in each subsequent Reporting Period.

3. *Periodic Training*. In addition to the Specific Training described above, Extendicare shall provide four hours of Periodic Training to all Relevant Covered Persons annually on the quality of care issues identified by the Compliance Committee. In determining what training should be performed, the Compliance Committee shall review the complaints received, satisfaction surveys, staff turnover data, any state or federal surveys, including those performed by the Joint Commission or other such private agencies, any internal surveys, the CMS quality indicators, and the findings, reports, and recommendations of the Monitor.

4. *Competency Based Training.* All Specific and Periodic Training required in this section shall be competency-based. Specifically, the training must be developed and provided in such a way as to focus on Relevant Covered Persons achieving learning outcomes to a specified competency and to place emphasis on what a Relevant Covered Person has learned as a result of the training.

5. *Board Member Training*. Within 90 days after the Effective Date, Extendicare shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

6. *Certification.* Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials and documentation evidencing that the individual attained competency in the required training areas. These shall be made available to OIG, upon request.

7. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

8. *Update of Training.* Extendicare shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or by the Independent Monitor, and any other relevant information.

9. *Computer-based Training.* Extendicare may provide the training required under this CIA through appropriate computer-based training approaches. If Extendicare chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Review Procedures

1. *General Description*

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, Extendicare shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.D. The IRO may retain additional personnel, including consultants, if needed to help meet the IRO's obligations under the CIA. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Retention of Records*. The IRO and Extendicare shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Extendicare) related to the reviews.

2. *Minimum Data Set (MDS) Review.* The IRO shall review Extendicare's coding, billing, and claims submission to Medicare Part A and the reimbursement received (MDS Review) and shall prepare a MDS Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Validation Review*. In the event OIG has reason to believe that: (a) Extendicare's MDS Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or MDS Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the MDS Review complied with the requirements of the CIA and/or the findings or MDS Review are inaccurate (Validation Review). Extendicare shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Extendicare's final Annual Report shall be initiated no later than one year after Extendicare's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Extendicare of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Extendicare may request a meeting with OIG to: (a) discuss the results of any MDS Review submissions or findings; (b) present any additional information to clarify the results of the MDS Review or to correct the inaccuracy of the MDS Review; and/or (c) propose alternatives to the proposed Validation Review. Extendicare agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any MDS Review issues with Extendicare prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

6. *Independence and Objectivity Certification*. The IRO shall include in its report(s) to Extendicare a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

E. Independent Monitor

Within 60 days after the Effective Date, Extendicare shall retain an appropriately qualified monitoring team (the "Monitor"), selected by OIG after consultation with Extendicare. The Monitor may retain additional personnel, including, but not limited to, independent consultants, if needed to help meet the Monitor's obligations under this CIA. The Monitor may confer and correspond with Extendicare or OIG individually or together. The Monitor and Extendicare shall not negotiate or enter into a financial relationship, other than the monitoring engagement required by this section, until after the date of OIG's CIA closure letter to Extendicare or six months after the expiration of this CIA, whichever is later.

The Monitor is not an agent of OIG. However, the Monitor may be removed by OIG at its sole discretion. If the Monitor resigns or is removed for any other reasons prior to the termination of the CIA, Extendicare shall retain, within 60 days of the resignation or removal, another Monitor selected by OIG, with the same functions and authorities.

1. *Scope of Review.* The Monitor shall be responsible for assessing the effectiveness, reliability, and thoroughness of the following:

a. Extendicare's internal quality control systems, including, but not limited to:

i. whether the systems in place to promote quality of care and to respond to quality of care issues are operating in a timely and effective manner;

ii. whether the communication system is effective, allowing for accurate information, decisions, and results of decisions to be transmitted to the proper individuals in a timely fashion; and

iii. whether the training programs are effective, thorough, and competency-based.

b. Extendicare's response to quality of care issues, which shall include an assessment of:

i. Extendicare's ability to identify the issue;

ii. Extendicare's ability to determine the scope of the issue, including, but not limited to, whether the problem is isolated or systemic;

iii. Extendicare's ability to conduct a root cause analysis;

iv. Extendicare's ability to create an action plan to respond to the issue;

v. Extendicare's ability to execute the action plan; and

vi. Extendicare's ability to monitor and evaluate whether the assessment, action plan, and execution of that plan was effective, reliable, and thorough.

c. Extendicare's proactive steps to ensure that each resident receives care in accordance with:

i. professionally recognized standards of health care;

ii. the rules and regulations set forth in 42 C.F.R. Part 483;

iii. State and local statutes, regulations, and other directives or guidelines; and

iv. the Policies and Procedures adopted by Extendicare, including those implemented under Section III.B of this CIA;

d. Extendicare's Staffing Committee and compliance with staffing requirements;

e. Extendicare's rehabilitation therapy systems, which shall include an assessment of whether such systems ensure Extendicare:

i. provides only skilled rehabilitation therapy that is: (1) delivered pursuant to a physician's

orders and to an individualized plan of care including documented therapy goals; (2) consistent with the nature and severity of the resident's individual illness or injury; (3) in compliance with accepted standards of medical practice; (4) reasonable and necessary to improve a resident's current condition, to maintain the resident's current condition, or to prevent or slow further deterioration of the resident's condition; and (5) limited to services that require the skills of physical, speech, or occupational therapists, among other types of professionals and that must be provided directly by or under the general supervision of these skilled rehabilitation personnel to assure the safety of the resident and to achieve the medically desired result;

ii. complies with Medicare program requirements relating to the tracking of therapy minutes; and

iii. complies with all Medicare guidance on appropriate documentation of medical records.

f. Extendicare's ability to analyze outcome measures, such as the CMS Quality Indicators, and other data; and

g. Extendicare's Quality of Care Dashboard required under Section III.A.2.c. of this CIA.

Access. The Monitor shall have:

a. immediate access to Extendicare, at any time and without prior notice, to assess compliance with this CIA, to assess the effectiveness of the internal quality assurance mechanisms, and to ensure that the data being generated is accurate;

b. immediate access to:

i. the CMS quality indicators;
ii. internal or external surveys or reports;
iii. Disclosure Program complaints;

iv. resident satisfaction surveys;

v. staffing data in the format requested by the Monitor, including reports detailing when more than 10 percent of Extendicare's staff are hired on a temporary basis;

vi. reports of abuse, neglect, or any incident that required hospitalization or emergency room treatment;

vii. reports of any falls;

viii. reports of any incident involving a resident that prompts a full internal investigation;

ix. resident records;

x. documents in the possession or control of any quality assurance committee, peer review committee, medical review committee, or other such committee; and

xi. any other data in the format the Monitor determines relevant to fulfilling the duties required under this CIA;

c. immediate access to residents, and Covered Persons for interviews outside the presence of Extendicare supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the rights of such individuals. The Monitor shall give full consideration to an individual's clinical condition before interviewing a resident.

3. *Baseline Systems Assessment.* Within 60 days after the Monitor is retained by Extendicare or 120 days after the Effective Date of the CIA, whichever is later, the Monitor shall:

a. complete an assessment of the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.E.1;

b. in conducting this assessment, visit Extendicare's facilities (selected by the Monitor) and, at a minimum, observe care planning meetings, interview key employees, review relevant documents, observe resident care; and observe corporate level committee meetings such as: Compliance Committee, Staffing Committee, and Board of Directors Committee meetings; and

c. submit a written report to Extendicare and OIG that sets forth, at a minimum:

i. a summary of the Monitor's activities in conducting the assessment;

ii. the Monitor's findings regarding the effectiveness, reliability, scope, and thoroughness of each of the systems described in Section III.E.1; and

iii. the Monitor's recommendations to Extendicare as to how to improve the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.E.1.

4. *Systems Improvements Assessments.* On a quarterly basis, the Monitor shall:

a. re-assess the effectiveness, reliability, and thoroughness of the systems described in Section III.E.1;

b. assess Extendicare's response to recommendations made in prior written assessment reports;

c. in conducting this assessment, visit Extendicare's facilities (selected by the Monitor) and, at a minimum, observe care planning meetings, interview key employees, review relevant documents, observe resident care; and observe corporate level committee meetings such as: Compliance Committee, Staffing Committee, and Board of Directors Committee

meetings (the Monitor may also want to have regular telephone calls with Extendicare and any of its poorer performing facilities); and

b. submit a written report to Extendicare and OIG that sets forth, at a minimum:

i. a summary of the Monitor's activities in conducting the assessment;

ii. the Monitor's findings regarding the effectiveness, reliability, scope, and thoroughness of each of the systems described in Section III.E.1;

iii. the Monitor's recommendations to Extendicare as to how to improve the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.E.1; and

iv. the Monitor's assessment of Extendicare's response to the Monitor's prior recommendations.

For the first Reporting Period, the Monitor shall perform assessments for each quarter or portion of a quarter not covered by the Baseline Systems Assessment. For each subsequent Reporting Period, the Monitor shall perform quarterly assessments. The Monitor shall submit written reports no later than 30 days after the end of the relevant quarter to Provider and OIG.

5. *Financial Obligations of Extendicare and the Monitor*.

a. Extendicare shall be responsible for all reasonable costs incurred by the Monitor in connection with this engagement, including, but not limited to, labor costs (direct and indirect); consultant and subcontract costs; materials cost (direct and indirect); and other direct costs (travel, other miscellaneous).

b. Extendicare shall pay the Monitor's bills within 30 days of receipt. Failure to pay the Monitor within 30 calendar days of submission of the Monitor's invoice

for services previously rendered shall constitute a basis to impose stipulated penalties or exclude Extendicare, as provided under Section X of the CIA. While Extendicare must pay all of the Monitor's bills within 30 days, Extendicare may bring any disputed Monitor's Costs or bills to OIG's attention.

c. The Monitor shall charge a reasonable amount for its fees and expenses, and shall submit monthly invoices to Extendicare with a reasonable level of detail reflecting all key category costs billed.

d. The Monitor shall submit a written report for each Reporting Period representing an accounting of its costs throughout the year to Extendicare and to OIG by the submission deadline of Extendicare's Annual Report. This report shall reflect, on a cumulative basis, all key category costs included on monthly invoices.

6. *Additional Extendicare Obligations.* Extendicare shall:

a. As a condition of retaining the Monitor, Extendicare shall require the Monitor to enter into a subcontract with an individual or entity, approved by OIG, that can create objective and independent Quality Indicator data analysis reports of the type described in the attached Appendix C;

b. within 30 days after receipt of each written report of the Baseline Systems Assessment or Systems Improvement Assessments, submit a written response to OIG and the Monitor to each recommendation contained in those reports stating what action Extendicare took in response to each recommendation or why Extendicare has elected not to take action based on the recommendation;

c. provide the Monitor a report monthly, or sooner if requested by the Monitor, regarding each of the following occurrences:

i. Deaths or injuries related to use of restraints;

ii. Deaths or injuries related to use of psychotropic medications;

iii. Suicides;

iv. Deaths or injuries related to abuse or neglect (as defined in the applicable federal guidelines);

v. Fires, storm damage that poses a threat to residents or otherwise may disrupt the care provided, flooding, or major equipment failures at Extendicare;

vi. Strikes or other work actions that could affect resident care;

vii. Man-made disasters that pose a threat to residents (e.g., toxic waste spills); and

viii. Any other incident that involves or causes actual harm to a resident when such incident is required to be reported to any local, state, or federal government agency.

Each such report shall contain, if applicable, the full name, social security or medical record number, and date of birth of the resident involved, the date of death or incident, and a brief description of the events surrounding the death or incident.

d. provide to its Compliance Committee and Board of Directors Committee copies of all documents and reports provided to the Monitor, or if appropriate, compilations and summaries of such documents or reports;

e. ensure the Monitor's immediate access to the facility, residents, Covered Persons, and documents, and assist in obtaining full cooperation by its current employees, contractors, and agents;

f. provide access to current residents and provide contact information for their families and guardians consistent with the rights of such individuals under state or federal law, and not impede their cooperation with the Monitor;

g. assist in locating and, if requested, attempt to obtain cooperation from past employees, contractors, agents, and residents and their families;

h. provide the last known contact information for former residents, their families, or guardians consistent with the rights of such individuals under state or federal law, and not impede their cooperation; and

i. not sue or otherwise bring any action against the Monitor related to any findings made by the Monitor or related to any exclusion or other sanction of Extendicare under this CIA; provided, however, that this clause shall not apply to any suit or other action based solely on the dishonest or illegal acts of the Monitor, whether acting alone or in collusion with others.

7. *Additional Monitor Obligations*. The Monitor shall:

a. abide by all state and federal laws and regulations concerning the privacy, dignity, and employee rights of all Covered Persons, and residents;

b. abide by the legal requirements of Extendicare to maintain the confidentiality of each resident's personal and clinical records. Nothing in this subsection, however, shall limit or affect the Monitor's obligation to provide information, including information from resident clinical records, to OIG, and, when legally or professionally required, to other agencies;

c. at all times act reasonably in connection with its duties under the CIA including when requesting information from Extendicare;

d. if the Monitor has concerns about action plans that are not being enforced or systemic problems that could affect Extendicare's ability to render quality care to its residents, then the Monitor shall:

   i. report such concerns in writing to OIG; and

   ii. simultaneously provide notice and a copy of the report to Extendicare's Compliance Committee and Board of Directors Committee referred to in Section III.A of this CIA;

e. where independently required to do so by applicable law or professional licensing standards, report any finding to an appropriate regulatory or law enforcement authority, and simultaneously submit copies of such reports to OIG and to Extendicare;

f. not be bound by any other private or governmental agency's findings or conclusions, including, but not limited to, Joint Commission, CMS, or the state survey agency. Likewise, such private and governmental agencies shall not be bound by the Monitor's findings or conclusions. The Monitor's reports shall not be the sole basis for determining deficiencies by the state survey agencies. The parties agree that CMS and its contractors shall not introduce any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence into any proceeding involving a Medicare or Medicaid survey, certification, or other enforcement action against Extendicare, and Extendicare shall similarly be restricted from using material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence in any of these proceedings. Nothing in the previous sentence, however, shall preclude OIG or Extendicare from using any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor in any action under the CIA or pursuant to any other OIG authorities or in any other situations not explicitly excluded in this subsection;

g. abide by the provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 to the extent required by law including, without limitation, entering into a business associate agreement with Extendicare; and

h. except to the extent required by law, maintain the confidentiality of any proprietary financial and operational information, processes, procedures, and forms obtained in connection with its duties under this CIA and not comment publicly concerning its findings except to the extent authorized by OIG.

F. Disclosure Program

Within 90 days after the Effective Date, Extendicare shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Extendicare's policies, conduct, practices, or procedures with respect to quality of care or a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Extendicare shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees and by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper conduct or practice; and (2) provides an opportunity for taking corrective action, Extendicare shall conduct an internal review of the allegations set forth in the disclosure and ensure that corrective action is taken and proper follow-up is conducted. If the inappropriate or improper conduct or practice places residents

at risk of harm, then Extendicare will ensure that the conduct or practice ceases immediately and that appropriate action is taken.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be sent to the Monitor not less than monthly unless otherwise agreed to in writing by OIG and the Monitor.

G. Ineligible Persons

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's System for Award Management (available through the Internet at http://www.sam.gov).

2. *Screening Requirements*. Extendicare shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements:

a. Extendicare shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. Extendicare shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Extendicare shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in Section III.G affects Extendicare's responsibility to refrain from (or its liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Extendicare understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Extendicare may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Extendicare meets the requirements of Section III.G.

3. *Removal Requirement*. If Extendicare has actual notice that a Covered Person has become an Ineligible Person, Extendicare shall remove such Covered Person from responsibility for, or involvement with the delivery of resident care or Extendicare's business operations related to the Federal health care programs, and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If Extendicare has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Extendicare shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect

either the quality of care rendered to any beneficiary, resident, or any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, Extendicare shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Extendicare conducted or brought by a governmental entity or its agents involving an allegation that Extendicare has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Extendicare shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

In addition, within 15 days after notification, Extendicare shall notify OIG, in writing, of any adverse final determination made by a federal, state, or local government agency or accrediting or certifying agency (e.g., Joint Commission) relating to quality of care issues.

I. Repayment of Overpayments

1. *Definition of Overpayments*. For purposes of this CIA, an "Overpayment" shall mean the amount of money Extendicare has received in excess of the amount due and payable under any Federal health care program requirements.

2. *Repayment of Overpayments*

a. If, at any time, Extendicare identifies any Overpayment, Extendicare shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) within 60 days after identification of the Overpayment and take remedial steps within 90 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified, within 60 days after identification, Extendicare shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification

and repayment to the payor shall be done in accordance with the payor's policies.

b. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

J. Reportable Events

1. *Definition of Reportable Event*. For purposes of this CIA, a "Reportable Event" means anything that involves:

a. a substantial Overpayment;

b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

c. a matter that a reasonable person would consider a probable violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances and presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations;

d. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

e. insolvency or a matter that a reasonable person would consider likely to render Extendicare insolvent.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events*. If Extendicare determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that a Reportable Event has occurred, Extendicare shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.J.1.a*. For Reportable Events under Section III.J.1.a, the report to OIG shall be made at the same time as repayment to the payor required in Section III.I, and shall include:

a. a copy of the notification and repayment to the payor required in Section I.2;

b. a description of the steps taken by Extendicare to identify and quantify the Overpayment;

c. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

d. a description of Extendicare's actions taken to correct the Reportable Event; and

e. any further steps Extendicare plans to take to address the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.J.1.b and d*. For Reportable Events under Section III.J.1.b and d, the report to OIG shall include:

a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

b. a description of Extendicare's actions taken to correct the Reportable Event;

c. any further steps Extendicare plans to take to address the Reportable Event and prevent it from recurring; and

d. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Extendicare to identify and quantify the Overpayment.

5. *Reportable Events under Section III.J.1.c.* For Reportable Events under Section III.J.1.c, the report to OIG shall include:

a. a complete description of the Reportable Event, including the relevant facts, persons involved, the impact or potential impact on Federal health care program beneficiaries, and any legal and Federal health care program authorities implicated;

b. a description of Extendicare's action taken to correct the Reportable Event;

c. any further steps Extendicare plans to take to address the Reportable Event and prevent it from reoccurring; and

d. a summary of any related reports made to Federal or state regulatory or enforcement agencies or to professional licensing bodies.

6. *Reportable Events under Section III.J.1.e.* For Reportable Events under Section III.I.1.e, the report to OIG shall include:

a. a complete description of the Reportable Event;

b. a description of Extendicare's action taken to ensure that the Reportable Event does not adversely impact resident care;

c. any further steps Extendicare plans to take to address the Reportable Event; and

d. if the Reportable Event involves the filing of a bankruptcy petition, documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

7. Reportable Events Involving the Stark Law. Notwithstanding the reporting requirements outlined above, any Reportable Event that solely

involves a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Extendicare to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.I.2 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP. If Extendicare identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Extendicare is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY: CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Extendicare changes locations or closes a business unit or location that is subject to this CIA (as defined in Section II.B), Extendicare shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Extendicare purchases or establishes a new business unit or location that is subject to this CIA as set forth in Section II.B, Extendicare shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number, the location's Medicare and state Medicaid program provider number and/or supplier number(s), and the name and address of each Medicare and state Medicaid program contractor to which Extendicare currently submits claims. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale or Transfer of Unit or Location. In the event that, after the Effective Date, Extendicare proposes to sell or transfer any or all of its business units or locations that are subject to this CIA (as defined in Section II.B), Extendicare shall notify OIG of the proposed sale or transfer at least 30 days prior to the sale or transfer of such business unit or location. This notification shall include a description of the business unit or location to be sold or transferred, a brief description of the terms of the transaction, and the name and contact information of the prospective purchaser or transferee. This CIA shall be binding on the purchaser or transferee of such business unit or location, unless otherwise determined and agreed to in writing by OIG. This CIA shall bind the purchaser or transferee only with respect to those business units or locations that are being sold

or transferred by Extendicare to such a purchaser or transferee and not with respect to any other business unit or location owned or operated by the purchaser or transferee.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Extendicare shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A;

3. the names and positions of the members of the Board of Directors Committee required by Section III.A;

4. a description of the Quality of Care Review Program required by Section III.A;

5. a description of the Dashboard required by Section III.A;

6. the names and positions of the members of the Staffing Committee required by Section III.A; III.B.1;

7. a copy of Extendicare's Code of Conduct required by Section

8. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

9. a summary of all Policies and Procedures required by Section III.B.2 (a copy of such Policies and Procedures shall be made available to OIG upon request);

10. the following information regarding each type of training required by Section III.C:

a. a description of such training, including the targeted audience, the categories of personnel required to participate in the training, a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be made available to OIG, upon request.

11. a description of the Disclosure Program required by Section

12. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between Extendicare and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Extendicare;

13. a description of the process by which Extendicare fulfills the requirements of Section III.G regarding Ineligible Persons;

14. a list of all of Extendicare's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Extendicare currently submits claims;

15. a description of Extendicare's corporate structure, including identification of any individual owners and investors, real estate investment trusts, land ownership, parent and sister companies, subsidiaries, affiliates, and their respective lines of business;

16. the certification required by Section V.C; and

17. a copy of the Board of Directors Committee Resolution required by Section III.A.3.b.

B. Annual Reports. Extendicare shall submit to OIG annually a report with respect to the status of, and findings regarding, Extendicare's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other non-compliance job responsibilities of the Compliance Officer; any change in the membership of the Compliance Committee or Board of Directors Committee; and any change in the membership of the Staffing Committee described in Section III.A;

2. a summary of activities, assessments, and recommendations under Extendicare's Quality of Care Review Program and a summary of any corrective action taken in response to any issues identified through its Quality of Care Review Program;

3. a summary of the Compliance Committee's measurement, analysis, and tracking of the performance metrics included in Extendicare's Dashboard, Extendicare's progress towards its quality improvement goals, and any changes to the Dashboard and the reasons for such changes;

4. the Board of Directors Committee Resolution required by

5. a summary of activities, assessments, and recommendations and findings of the Staffing Committee required by Section III.A, and a summary of Extendicare's responses to any recommendations made by the Staffing Committee;

6. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG, upon request);

7. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);

8. the following information regarding each type of training required by Section III.C:

a. a description of such training, including the targeted audience, the categories of personnel required to participate in the training, a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

A copy of all training materials and the documentation to support this information shall be made available to OIG, upon request.

9. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter;

10. Extendicare's response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports;

11. a summary and description of any and all current and prior engagements and agreements between Extendicare and the IRO (if different from what was submitted as part of the Implementation Report);

12. a certification from the IRO regarding its professional independence and objectivity with respect to Extendicare;

13. Extendicare's response and action plan(s) related to any written recommendations of the Monitor pursuant to Section III.E;

14. a copy of the disclosure log required under Section III.F (excluding any communications that relate solely to human resources issues);

15. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

16. any changes to the process by which Extendicare fulfills the requirements of Section III.G regarding Ineligible Persons;

17. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

18. a description of all changes to the most recently provided list of Extendicare's locations (including addresses) as required by Section V.A.14; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Extendicare currently submits claims; and

19. the certification required by Section V.C; and

20. the dates of each report made by the Compliance Officer and Compliance Committee to the Board (written documentation of such reports shall be made available upon request).

The first Annual Report shall be received by OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

Within 180 days of the submission of each Annual Report, Extendicare shall participate in an in-person meeting with a representative of OIG to review Extendicare's performance under the CIA. OIG, in its discretion, may waive this meeting requirement.

C. Certifications

The Implementation Report and Annual Reports shall include certification by the Compliance Officer, that:

a. to the best of his or her knowledge, except as otherwise described in the applicable report, Extendicare is in compliance with all of the requirements of this CIA; and

b. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes

that the information in the Report is accurate and truthful.

The first Annual Report shall include a certification by the Chief Financial Officer that, to the best of his or her knowledge, Extendicare has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information. Extendicare shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Extendicare shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Extendicare:

Donna Thiel
Vice President and Chief Compliance Officer

111 W. Michigan Street
Milwaukee, WI 53203
Telephone: (414) 908-8119

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Extendicare may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Extendicare's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Extendicare's locations that are covered by this CIA for the purpose of verifying and evaluating: (a) Extendicare's compliance with the terms of this CIA; and (b) Extendicare's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Extendicare to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Extendicare's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Extendicare shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Extendicare's employees may elect to be interviewed with or without a representative of Extendicare present.

VIII. DOCUMENT AND RECORD RETENTION

Extendicare shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Extendicare prior to any release by OIG of information submitted by Extendicare pursuant to its obligations under this CIA and identified upon submission by Extendicare as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Extendicare shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Extendicare is expected to fully and timely comply with all of its CIA obligations.

A. Specific Performance of CIA Provisions. If OIG determines that Extendicare is failing to comply with a provision or provisions of this CIA and decides to seek specific performance of any of these provisions, OIG shall provide Extendicare with prompt written notification of such determination. (This notification shall be referred to as the "Noncompliance Notice.") Extendicare shall have 35 days from receipt of the Noncompliance Notice within which to either: (1) cure the alleged failure to comply; or (2) reply in writing that Extendicare disagrees with the determination of noncompliance and request a hearing before an HHS Administrative Law Judge (ALJ), pursuant to the provisions set forth in Section X.F of this CIA.

B. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Extendicare and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Extendicare fails to establish and effectively implement any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. the Board of Directors compliance obligations;

d. a Quality of Care Review Program;

e. a Quality of Care Dashboard;

f. a Staffing Committee;

g. a written Code of Conduct;

h. written Policies and Procedures;

i. the training of Covered Persons, Relevant Covered Persons, and Board Members in the manner required by Section III.C;

j. retention of a Monitor;

k. a Disclosure Program;

l. Ineligible Persons screening and removal requirements;

m. notification of Government investigations or legal proceedings; and

n. reporting of Reportable Events.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the day the obligation became due) for each day Extendicare fails to engage and use an IRO, as required in Section III.D, Appendix A, and Appendix B.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Extendicare fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Extendicare fails to submit any MDS Review Report in accordance with the requirements of Section III.D and Appendix B.

5. A Stipulated Penalty of $1,500 for each day Extendicare fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Extendicare fails to grant access.)

6. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of Extendicare as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Extendicare fails to pay a Monitor, as required in Section III.E.5.

8. A Stipulated Penalty of $2,500 for each day Extendicare fails to comply fully and adequately with any of its obligations with respect to the Monitor, including, but not limited to, the obligation to adequately and timely respond to any written recommendation of the Monitor, as set forth in Section III.E.6. OIG shall provide notice to Extendicare stating the specific grounds for its determination that Extendicare has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Extendicare shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Extendicare receives this notice from OIG of the failure to comply.)

9. A Stipulated Penalty of $1,000 for each day Extendicare fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Extendicare stating the specific grounds for its determination that Extendicare has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Extendicare shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Extendicare receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-8 of this Section.

C. Timely Written Requests for Extensions. Extendicare may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Extendicare fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Extendicare receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing

received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

D. Payment of Stipulated Penalties

1. *Demand Letter*. Upon a finding that Extendicare has failed to comply with any of the obligations described in Section X.B and after determining that Stipulated Penalties are appropriate, OIG shall notify Extendicare of: (a) Extendicare's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Extendicare shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS ALJ to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.F. In the event Extendicare elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Extendicare cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.E.

3. *Form of Payment*. Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination*. Except as set forth in Section X.E.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Extendicare has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.E, below.

E. Exclusion for Material Breach of this CIA

means:

1. *Definition of Material Breach*. A material breach of this CIA

a. a failure by Extendicare to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Sections III.I and III.J;

b. a repeated or flagrant violation of any obligation under this CIA, including, but not limited to, the obligations addressed in Section X.B;

c. a violation of any obligation under this CIA that has a material impact on the quality of resident care;

d. a failure to respond to a Noncompliance Notice concerning specific performance in accordance with Section X.A;

e. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.D; or

f. a failure to use an IRO in accordance with Section III.D, Appendix A, and Appendix B;

g. a failure to retain, pay, or use the Monitor, or failure to respond to the recommendations of the Monitor, in accordance with Section III.E.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by Extendicare constitutes an independent basis for Extendicare's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Extendicare has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Extendicare of: (a) Extendicare's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.") The exclusion may be directed at one or more of Extendicare's facilities, locations, or corporate entities, depending upon the facts of the breach.

3. *Opportunity to Cure*. Extendicare shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Extendicare is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Extendicare has begun to take action to cure the material breach; (ii) Extendicare is pursuing such action with due diligence; and (iii) Extendicare has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30-day period, Extendicare fails to satisfy the requirements of Section X.E.3, OIG may exclude Extendicare from participation in the Federal health care programs. OIG shall notify Extendicare in writing of its determination to exclude Extendicare. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.F, below, the exclusion shall go into effect 30 days after the date of Extendicare's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Extendicare may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

F. Dispute Resolution

1. *Review Rights*. Upon OIG's delivery to Extendicare of its Noncompliance Notice, Demand Letter, or Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Extendicare shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the specific performance, Stipulated Penalties, or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand specific performance, payment of Stipulated Penalties, or seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving specific performance or Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Specific Performance Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for specific performance of CIA provisions shall be:

a. whether, at the time specified in the Noncompliance Notice, Extendicare was in material compliance with the obligations of this CIA for which OIG seeks specific performance; and

b. whether Extendicare failed to cure to OIG's satisfaction.

Extendicare shall have the burden of proving its material compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to specific performance. If the ALJ agrees with OIG, Extendicare shall take the actions OIG deems necessary to cure within 20 days after the ALJ issues such a decision unless Extendicare requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, Extendicare shall take the actions OIG deems necessary to cure within 20 days after the DAB issues its decision.

3. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Extendicare was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Extendicare shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Extendicare to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Extendicare requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

4. *Exclusion Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only

issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether Extendicare was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Extendicare had begun to take action to cure the material breach within that period; (ii) Extendicare pursued and is pursuing such action with due diligence; and (iii) Extendicare provided to OIG within that period a reasonable timetable for curing the material breach and Extendicare followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Extendicare, only after a DAB decision in favor of OIG. Extendicare's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Extendicare upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Extendicare may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Extendicare shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Extendicare, Extendicare shall be reinstated effective on the date of the original exclusion.

5. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Extendicare and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Extendicare.

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

D. OIG may agree to a suspension of Extendicare's obligations under this CIA based on a certification by Extendicare that it is no longer providing health care items or services that will be billed to any Federal health care program and that it does not have any ownership or control interest, as defined in 42 U.S.C. § 1320a-3, in any entity that bills any Federal health care program. If Extendicare is relieved of its CIA obligations, Extendicare will be required to notify OIG in writing at least thirty (30) days in advance if Extendicare plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

E. The undersigned Extendicare signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

G. This CIA is by and between the parties hereto. The CIA is not intended to establish any legal rights for or confer any legal rights upon any non-governmental entities or persons not a party to the CIA. The parties agree, however, that this CIA is a public document and it may be admissible in a judicial or administrative proceeding.

ON BEHALF OF EXTENDICARE

/Tim Lukenda/	10/2/14
TIM LUKENDA President and Chief Executive Officer Extendicare Health Service, Inc.	DATE
/Glenn P. Hendrix/	10/2/14
GLENN P. HENDRIX Arnall Golden Gregory LLP	DATE
/J. Richard Kiefer/	10/3/14
J. RICHARD KIEFER Bingham Greenebaum Doll LLP	DATE

ON BEHALF OF THE PROGRESSIVE STEP CORPORATION

/Tim Lukenda/ 10/2/14

TIM LUKENDA
President and Chief Executive Officer
Extendicare Health Service, Inc.

DATE

/Glenn P. Hendrix/ 10/2/14

GLENN P. HENDRIX
Arnall Golden Gregory LLP

DATE

/J. Richard Kiefer/ 10/3/14

J. RICHARD KIEFER
Bingham Greenebaum Doll LLP

DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

/Robert K. DeConti/ 10/3/14

ROBERT K. DECONTI DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

/Tonya Keusseyan/ 9/30/14

TONYA KEUSSEYAN DATE
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

APPENDIX C - Table of State Mandatory Minimum Staffing Requirements

Appendix C – Table of State Mandatory Minimum Staffing Requirements[115]

State	Definition of "Sufficient Staff"	Licensed Staffing Requirements[116]	Direct Care Staffing Requirements
Federal		1 RN 8 consecutive hrs/7 days/wk & 1 RN/LVN for 2 remaining shifts. Must have 1 RN who is full-time DON (5 days/wk); if fewer than 60 residents, DON may also be Charge Nurse. (For 100 residents, LN .30 hours per resident day (hprd) would be required.)	
AK	To meet the needs of the residents	(RN, LPN/LVN) For 1-60 occupied beds: 1 RN Day 7days/wk and 1 RN Eve 5 d/wk and 1 LPN all shifts when RN not present For 60+ occupied beds: 2 RNs Day 7d/wk and 1 RN Eve & Night 7 days/week	No minimum requirement
AL	To attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident as determined by resident assessments and individual care plans.	(RN, LPN/LVN) 1 DON RN full-time included in 1 RN 8 consecutive hrs/7ds/wk For 1-60 residents: DON may be charge nurse	No minimum requirement
AR	To meet the needs of the residents for nursing services	(RN, LPN/LVN) 1 DON RN full-time Days; if has other responsibilities, add 1 more RN as Asst. DON to equal one FTE 1 RN or LPN Charge Nurse for each shift. 1-70 residents DON may be Charge Nurse In multi-story homes, staff each floor unit	1:6 ratio Days (total licensed or certified) 1:9 Evenings 1:14 Nights

[115] Adapted from Harrington, C., ppt of Nursing Home Staffing Standards in State Statutes and Regulations (December 2010).

[116] **Definitions and abbreviations key**:
DON = Director of Nursing – states may have their own requirements but the federal requirement is that a DON must be a licensed RN.
RN = Registered nurse - has a two-year degree, three-year diploma, four-year degree or more education and is licensed in a state.
LPN/LVN = Licensed practical nurse or licensed vocational nurse – has a one-year degree and is licensed in a state.
LN = A licensed nurse can be either an RN or an LVN/LPN.
NA = A nursing assistant or nurse's aide. If the NA has 75 hours of training and passes a competency exam, the NA can become a certified NA (CNA).
Hprd = Hours per resident day. **D**= Day shift. **E**= Evening shift. **N** = Night shift. **FT**= Full Time.
SC = State code or statutes. **SAL** = State administrative law or regulations. **SDP** = State written policy. **Eff.** = Effective on. **Ch**.= Chapter.

State	Definition of "Sufficient Staff"	Licensed Staffing Requirements[116]	Direct Care Staffing Requirements
		1:40 LN ratio Days and Evenings 1:80 LN ratio Nights	
AZ	To meet the needs of residents 24 hours a day.	(RN, LPN/LVN) 1 DON RN full-time; For 1-60 average daily census,: DON may provide direct care on regular basis	1 nurse for direct care to not more than 64 residents at all times.
CA	To meet the needs of residents.	(RN, LPN/LVN) For 1-59 licensed beds: 1 RN/LVN 24 hours/day For 60-99 licensed beds: 1 DON RN Day full-time (may not be charge nurse) and 1 RN/LVN 24 hours/day For 100+ beds: 1 DON RN (may not be charge nurse) and 1 RN 24 hours/day	3.2 hprd Do not double hours of RNs/LPNs and exclude hours of DON
CO	To provide prompt assistance to persons needing or potentially needing assistance and considering individual needs.	(RN, LPN/LVN) 1 DON RN full-time 40 hrs/wk included in 1 RN 24 hours/7days/week and 1 LN each care unit at all times	For 1-60 residents: 2.0 hprd For 60+ residents: 2.0 excluding the DON, staff development coordinator, and other supervisory personnel.
CT	To provide appropriate care 24 hours 7 days/week.	(RN, LPN/LVN) 1 DON RN full-time; if more than 120 beds, 1 Asst. DON 1 RN 24 hours/7 days/week and 1 RN/LPN (each floor) 24 hrs/7days included in .47 LN hprd Day/ Evening (7 am - 9 pm) .17 LN hprd Evening/ Night (9 pm - 7 am) For 61-120 beds: exclude DON; for 121+ beds, exclude Asst. DON	1.40 total nursing & NA hprd (7am-9pm) .50 total & NA hprd (9pm-7am)
DC	To meet the nursing needs of all patients 24-hour licensed nursing services 7days a week.	(RN, LPN/LVN) 1DON RN full-time and 1 Nursing Supervisor (RN) at the facility 24hrs/7d/wk DON may serve as supervisor while on regular duty if less that 30 beds 1 RN/LPN Charge Nurse on each unit 24hrs/day If charge nurse is LPN, then must have access to an RN for consultation RN/LPN (planning, coordination, supervision at unit level) 1:35 ratio (0.23 hprd) Days 1:45 ratio (0.18 hprd) Evenings 1:50 ratio (0.16) Nights	(RN, LPN, or CNA) 3.5 hprd minimum 1:5 (1.6 hprd) Days 1:10 (0.8 hprd) Evenings 1:15 (0.53 hprd) Nights Minimum of 2 staff per unit per shift
DE	To meet the needs of each resident.	(RN, LPN/LVN) 1 Supervisory Nurse (DON) RN full-time 8hrs/7d/wk	3.28 hours of direct nursing care 1:8 DC ratio Days

State	Definition of "Sufficient Staff"	Licensed Staffing Requirements[116]	Direct Care Staffing Requirements
		1 RN on duty each shift, 7 days a week 1:15 LN ratio Days 1:23 LN ratio Evenings 1:40 LN Nights	1:10 DC ratio Evenings 1:20 DC ratio Nights
FL	To maintain the highest practicable physical, mental, and psychological well-being of each resident	(RN, LPN/LVN) 1 DON RN full-time. If DON has other responsibilities, add 1 full-time RN as Asst. DON For 121+ residents, add 1 Asst. DON RN 1 RN/LPN each shift included in: 1.0 LN hprd (24 hour average) Never below 1:40 LN ratio	2.9 DC hprd (24 hour average) minimum weekly average per day 1:20 DC ratio
GA	To provide care for each resident according to his or her needs.	(RN, LPN/LVN) 1 DON RN full-time Day; DON may direct other nearby nursing homes if those homes have 1 RN as full-time Asst. DON 1 RN/LPN in each 8-hr shift 24h/7d included in: RN/LPN to total nursing personnel ratio: 1:7	2.0 hprd DC
HI	To meet the needs of the residents.	(RN, LPN/ LVN) 1 RN full-time 24 hours/7 days/week	No minimum requirement
IA	To meet the needs of individual residents.	(RN, LPN/LVN) 1 RN/LPN Health Service Supervisor For 1-74 beds: if supervisor is LPN, RN must work 4 hrs/wk when LPN is on duty. For 75+ beds: supervisor must be RN and add 1 RN/LPN 24 hrs/7 days/week	2.0 hprd (computed on 7-day week) 20% RN/LPNs including time of Supervisor 2 people on duty at all times.
ID	To meet the total needs of residents.	(RN, LPN/LVN) 1 DON RN full-time (5d/wk) Day. If DON occupied with administration, then 1 RN Asst. DON. 1 Supervising Nurse, RN/LPN. For 1-59 residents: DON may be Supervisory Nurse For 1-59 residents: 1 RN 8 hrs Days & 1 LPN other 2 shifts 7days/wk For 60-89 residents: 1 RN Days & Evenings &1 LPN Nights 7 days/wk For 90+ residents: 1 RN 24hrs/7d/wk	2.4 hprd. For 1-59 residents: exclude DON but include supervisory nurse on each shift. For 60+ residents: exclude DON and supervisory nurse.
IL	To meet the needs of the residents.	(RN, LPN/LVN) 1 DON RN full-time or minimum 36 hours/week (at least 16 hrs between 7am and 7pm) For 1-49 beds, DON may provide direct care and be included in direct care ratios For 100+, 1 Asst. DON RN full-time. 1 licensed nurse (RN/LPN) charge nurse on remaining non-DON or Asst DON shifts. 1 RN on shift (8 consecutive hrs) 7days/wk included in 1 RN/LPN 24 hrs/7d/wk on each floor	2.5 hprd with Day-40%, Eve-25%, and Night-15%. Include 20% LN time; exclude DON and 1 person on duty 24h/7d in each unit Direct care staff includes: RNs, LPNs, CNAs, Psych aides, Rehab/Therapy aides, Psych

State	Definition of "Sufficient Staff"	Licensed Staffing Requirements[116]	Direct Care Staffing Requirements
			coordinators, Asst. DONs, 50% of DON, 30% of Social Service Director 2.5 hprd Eff. 7-1-10 2.7 hprd Eff. 1-1-11 3.0 hprd Eff. 1-1-12 3.4 hprd Eff. 1-1-13 3.8 hprd Eff. 1-1-14
IN	To maintain highest practicable physical, mental, and psychosocial well-being of each resident.	(RN, LPN/LVN) 1DON RN full-time included in 1 RN 8 consecutive hours/7days/wk and 1 LPN Charge Nurse each shift For 1-60 resident: DON may be Charge Nurse included in: RN/LPN ratio 0.5 LPN hprd to resident ratio (averaged over 1 week, excluding DON)	No minimum requirement
KS	To attain or maintain the highest practicable physical, mental and psychosocial well-being.	(RN, LPN/LVN) 1 DON RN full-time included in 1 RN at least 8 consecutive hours/day 7d/wk and 1 RN/LPN per nursing unit on Day Shift included in 1 RN/LPN 24 hours/7days/wk If 1 LPN on Day shift, 1 RN must be on call	2.0 hprd weekly average (with a 1.85 hprd minimum 24-hour average) For 60+ beds: exclude DON 1:30 minimum ratio and at least 2 nursing personnel on duty at all times
KY	To attain or maintain the highest practicable physical, mental & psychosocial well-being of each resident.	(RN, LPN/LVN) 1 DON RN full-time Day; may serve as charge nurse with occupancy less than 60 residents; If DON is facility administrator, add 1 Asst. DON RN Fulltime Days) 1 Supervising Nurse RN FT (DON or Asst. DON may be Supervising Nurse) 1 RN at least 8 hours/day, 7 days/wk 1 RN/LPN Charge Nurse 24 hrs/7days/wk; if LPN Charge Nurse, RN must be on call.	No minimum requirement
LA	To provide nursing care to all residents.	(RN, LPN/LVN) 1 DON RN full-time Day and (If DON has regular administrative responsibility add 1 Asst. DON RN full-time) For 1-60 average daily occupancy: DON may be charge nurse 1 RN/LPN Charge Nurse for each unit 24hrs/7days	1.5 hprd
MA	To meet the needs of residents and assure that measures, treatments and other activities and services are carried	(RN, LPN/LVN) 1 DON RN full-time (40 hours) Day and In multi-unit facilities: 1 RN FT Day Supervisor for up to two (2) units in the same facility. 1 RN/LPN Charge Nurse 24 hrs/7days/wk per unit	2.6 hprd including 0.6 licensed nurses (2.0 ancillary nursing personnel) - Level I 2.0 hprd including 0.6 licensed nurses (1.4

State	Definition of "Sufficient Staff"	Licensed Staffing Requirements[116]	Direct Care Staffing Requirements
	out, recorded, & reviewed.	0.6 licensed nurses for Level I and II facilities	ancillary nursing personnel) -- Level II No more than 12 hrs/day or 48 hrs/wk regularly.
MD	To provide appropriate bedside care to serve each resident.	(RN, LPN/LVN) 1 DON RN full-time included in RNs to residents (only bedside care may be counted): 2-99 residents: 1 RN full-time 100-199: 2 RNs full-time 200-299: 3 RNs full-time 300-399: 4 RNs full-time 1 LN on duty at all times	2.0 hprd 7 days/week (including LNs and supportive personnel and 50% ward clerk's time and only the documented bedside hours of DON 1:25 ratio at all times
ME	To meet the needs of residents as determined by their levels of care.	(RN, LPN/LVN) 1 DON RN full-time included in 1 RN 8 consecutive hrs, 7 d/wk on Days 1 RN/LPN Charge Nurse 7 d/wk on Days For 20+ beds: DON may not be Charge Nurse For 100, 150, 200 etc. beds: add 1 LN for each increment of 50 For 100+: for each multiple of 100, the additional LN shall be an RN and 1 RN/LPN Eve, on duty 8 hrs every eve. and 1 RN/LPN for multiples of 70 beds For 100+: one of additional LNs shall be an RN and 1 RN/LPN Night & 1 RN/LPN for multiples of 100 For 100+: an RN shall be on duty at night	1:5 ratio Days 1:10 ratio Evenings 1:15 ratio Nights Include RNs, LPNs, CNAs who provide direct care.
MI	To meet the needs of residents.	(RN, LPN/LVN) 1 DON RN (with training in gerontology) included in 1 RN/LPN 24 hrs/7d/wk	2.25 hprd or ratio of 1:8 ratio Days 1:12 ratio Evenings 1:15 ratio Nights For 30+ beds, exclude time of DON.
MN	To meet the needs of residents.	(RN, LPN/LVN) 1 DON RN full-time (at least 35 hrs) included in 1 RN/LPN 8 hrs/7 days/week Designate a nurse responsible for DON duties when DON is absent RN on call during all hours when an RN is not on duty.	2.0 hprd including all LNs and NAs for any 24 hour period. For 60+ licensed beds: exclude DON hours. 1 "responsible person" awake, dressed, and on duty at all times.
MO	To attain or maintain the highest practicable level of physical, mental and psychosocial well-being.	(RN, LPN/LVN) 1 DON RN included in 1 RN Day and 1 RN/LPN Eve & Night and 1 RN on call if only LPN on duty When DON is LPN, an RN should consult 4 hours per week.	No minimum requirement

State	Definition of "Sufficient Staff"	Licensed Staffing Requirements[116]	Direct Care Staffing Requirements
MS	No requirement.	(RN, LPN/ LVN) 1 DON RN full-time Day (40 hrs/wk) For 1-60 beds: DON may be Charge Nurse For 180+ beds: add 1 Asst DON RN included in 1 RN Day 7 days/week on day shift and 1 RN/LPN Charge Nurse Day & Eve and 1 RN/LPN Medication Nurse Day & Eve each station1 RN/LPN Charge Nurse & medication/treatment nurse Night on each station For 60+ beds: Charge Nurse may not be DON or Medication/Treatment Nurse	2.8 hprd for licensed and unlicensed staff 2 employees at all times
MT	To meet the nursing needs of the residents, reflecting current concepts of restorative and geriatric care.	(RN, LPN/LVN) 1 RN 8 hours 7days/wk 4-40 beds: 1 RN day, 1 LVN evening, 1 LVN nights For 41+ beds: 1 RN full-time DON included in For 41-75 beds: Add 1 LPN day, For 51-75 beds: Add 1 RN eve instead of LPN For 71-80 beds: Add 1 RN nights instead of LPN For 76-80 beds : 1 RN and 2 LPNs day, 1 RN and 1LPN eve, 1 RN nights For 81-90 beds: 1 RN and 2 LPNs day, 1 RN and 1 LPN eve and night For 91-100 beds: 2 RNs and 2 LPNs day, 1 RN and 1 LPN eve and 1 RN and 1 LPN night For 101+ beds: staffing is negotiable	(NA/CNA) 4 NA hours for every 5 residents per day on days For 9-75 beds, add 1 NA on days For 76-80 beds, 42 hours total For 81-85 beds, 52 NA hours For 86-90 beds, 56 NA hours For 91-95 beds, 52 hours For 96-100 beds, 56 hours 4 NA hours for 16+ beds on Eve increasing in increments of 4 NA hours for each additional 5 beds up to 70 beds, 32 hours for 66-90 beds, 36 for 91-95 beds, 40 NA hours for 195-100 beds 4 NA hours for 21+ beds on Night increasing in increments of 4 NA hours for every additional 5 beds up to 24 NA hours for 66-100 beds
NC	To accomplish the purposes of needs assessment, care planning and supervision	(RN, LPN/LVN) 1 DON RN included in 1 RN 8 consecutive hrs/7d/wk and 1 RN/LPN Charge Nurse 24hrs/7days/wk	No minimum requirement
ND	To meet the nursing needs of residents	(RN, LPN/LVN) 1 DON RN included in	No minimum requirement

State	Definition of "Sufficient Staff"	Licensed Staffing Requirements[116]	Direct Care Staffing Requirements
		1 RN 8 consecutive hrs/7d/wk and 1 RN/LPN Charge Nurse 24hrs/7days/wk	
NE	To meet the residents' needs personal care, activities of daily living, supervision, supportive services and medical care.	(RN, LPN/LVN) 1 DON RN full-time included in (cannot be waived) 1 RN 8 consecutive hrs/7days/wk and 1 RN/LPN Charge Nurse on each tour of duty 24 hrs/7days/week For 1-59 occupancy: DON may be Charge Nurse	No minimum requirement
NH	To attain the highest practicable physical, mental and psychosocial well-being of each resident.	(RN.,LPN/ LVN) 1 RN DON included in 1 RN 8 hours/7 days/week included in 1 RN/LPN 24 hours/7 days/week	No minimum requirement
NJ	No requirement.	(RN, LPN/LVN) 1 DON RN full-time and 1 RN alternate DON when regular DON absent For 150+ licensed beds: add 1 Asst. DON RN 1 RN on duty during all Day shifts and 1 RN on duty or on call all Eve. & Night shifts For 150+ beds: 1 RN 24hrs/7d/wk Plus advisory requirements for 200+ beds	2.5 hprd (exclude DON, but include DON's direct care hours in facilities with more than 1 FT DON) 20% of 2.5 hprd provided by RN/LPN Plus additional hprd for specified resident conditions or treatments
NM	To meet each resident's needs and implement each resident's comprehensive care plan.	(RN, LPN/LVN) 1 DON RN full-time Days included in 1 RN/LPN Charge Nurse 24 hrs/7d/wk DON may be the Charge Nurse	2.5 hprd 7 days a week on average 1:9-10 ratio average For example: 1:7 Days; 1:10 Evenings; 1:12 Nights. Include only direct care hrs of DON, Asst. DON, Nursing Department Director. 1 nursing staff person on duty at all times.
NV	To attain and maintain the highest practicable physical, mental and psychosocial well-being of each patient	(RN, LPN/LVN) 1 DON full-time RN included in 1 RN 8 consecutive hrs/ 7d/wk For 1-60 occupancy, DON may be Charge Nurse and 1 LPN Charge Nurse each shift	No minimum requirement
NY	To attain well-being of the residents 24 hours/day	(RN, LPN/LVN) 1 DON RN full-time included in 1 RN 8 consecutive hours/7d/wk 1 RN/LPN Charge Nurse 24 hours/7d/wk or 1 Charge Nurse for each unit or proximate units for each tour of duty For 1-60 occupancy, DON may serve as charge Nurse.	No minimum requirement

State	Definition of "Sufficient Staff"	Licensed Staffing Requirements[116]	Direct Care Staffing Requirements
OH	To provide adequate services and care at all times	(RN, LPN/LVN) 1 DON RN full-time (8 hours per day, between 6am&6pm) 5D/wk); Acting DON must be RN; 1-59 beds, DON may be counted in the staffing requirements. Minimum of 0.2 hprd RN time (NA/CNA) 2.0 hprd minimum	2.75 hprd minimum (2.0 hrpd NA; 0.2 hprd RN and LNs providing direct care) 1:15 ratio
OK	To meet the needs of all residents	(RN, LPN/LVN) 1 DON RN/LPN Day shift and available by phone 1 RN/LPN 8 hours 7 days/week and (if DON is LPN, at least 1 RN 8h/wk consultant) 1 RN/LPN on duty at all times	1:6 7am-3pm 1:8 3pm-11pm 1:15 11pm-7am If flexible staff scheduling, must maintain 2.86 hrs 7 days a week and 1:16 ratio with 2 staff on duty & awake at all times. Progressive increases in staffing (based on reimbursements) from 2.86 to 3.2 to 3.8 to 4.1 hrs/day per occupied bed
OR	To provide care to achieve highest degree of function.	(RN, LPN/LVN) 1 DON RN 1 RN/LPN Charge Nurse 24 hr/7d/wk including 1 RN Charge Nurse 8 consecutive hrs (7am -11pm) For 1-60 residents: DON may be Charge Nurse No less than 1 RN hour per resident per week. For 41+ beds: exclude hrs of RN administrator	(NA/CNA) Beginning April 1, 2009 1:7 Days 1:11 Evenings 1:18 Nights 2 staff on duty at all times
PA	To meet the needs of residents.	(RN, LPN/LVN) 1 DON RN full-time (1 per facility) and 1 RN Charge Nurse 24hrs/7d/wk For 1-59 residents: 1RN Day & Even; 1 RN/LPN Nights. If LPN is Charge Nurse, RN must be on call For 60-150 residents: 1 RN 24hr/7d/wk; For 151-250: 1 RN & 1 LPN 24 hr/7d; For 251-500: 2 RNs 24hr/7d For 501-1,000: 4 RN Day; 3 RN Eve & Nights For 1001+ residents: 8 RN Day; 6 RN Even & 6 Nights (NA/CNA) 1:20 nursing staff employees to residents 2 staff on duty at all times	2.7 hprd

State	Definition of "Sufficient Staff"	Licensed Staffing Requirements[116]	Direct Care Staffing Requirements
RI	To meet the needs of residents at all times	(RN, LPN/LVN) 1 DON RN full-time and (1 relief RN when DON absent) 1 RN on duty 24 hrs/7d/wk For 1-30 beds: DON may act as Charge Nurse	1 staff certified in basic life support available 24hrs/7d/wk No nursing staff of any facility shall be regularly scheduled for double shifts.
SC	To attain or maintain the highest practicable functioning and safety of each resident.	(RN, LPN/LVN) 1 DON RN full-time and For 1-22 beds: include DON in licensed staff 1 Licensed Nurse per work area per shift For 45+ residents per station: 2 LNs for first shift, and at least 1LN for second and third shift. At least 1 RN per facility 24hrs/7days OR on call	(NA/CNA) 1:9 Shift 1 1:13 Shift 2 1:22 Shift 3
SD	To meet the resident's total needs at all times.	(RN, LPN/LVN) 1 DON RN full-time and 1 RN/LPN Charge Nurse 24 hours/7days/wk For 1-59 residents: DON may be Charge Nurse. Ratio of LNs to NAs sufficient to provide supervision	No minimum requirement
TN	Adequate numbers to provide care as needed	(RN, LPN/LVN) 1 DON RN and 1 RN/LPN 24 hours/7days/week included in 0.4 hprd LNs	2.0 hprd including 0.4 hprd of LNs time 2 staff on duty each shift
TX	To provide care to all residents.	(RN, LPN/LVN) 1 DON RN full-time 40 hrs/wk included in For 1-60 occupancy: DON may be Charge Nurse 1 RN 8 consecutive hrs/7d/wk and 1 RN/LPN Charge Nurse 24hrs/7days/wk in 0.4 hprd LNs or 1:20 LNs every 24 hrs Exclude administrative time of licensed staff and DON in a multi-level facility	No minimum requirement
UT	To meet the needs of the residents.	(RN, LPN/LVN) 1 DON RN full-time 1 RN 8 consecutive hours/7days/wk included in 1 RN/LPN Charge Nurse each shift DON may not serve as Charge Nurse	No minimum requirement *Small Healthcare Facility* (4-16 beds) : 2.0 hprd (120 minutes) (RN + LPN + Aides) 20% by licensed staff (RN + LPN).
VA	To meet the assessed needs of all residents.	(RN, LPN/LVN) 1 DON RN full-time 5 days/wk For 1-59 beds: DON may be Nursing Supervisor 1 [RN/LPN] Nursing Supervisor	Qualified staff on all shifts 7d/wk No minimum requirement
VT	To attain or maintain the highest practicable physical,	(RN, LPN/LVN) 1 DON RN full-time included in 1 RN 8 consecutive hours/7d/wk and	3.0 hprd of which 2.0 hprd must be

State	Definition of "Sufficient Staff"	Licensed Staffing Requirements[116]	Direct Care Staffing Requirements
	mental, and psychosocial well-being of each residents.	1 RN/LPN Charge Nurse 24 hrs/7d/wk For 1-60 occupancy: DON may be Charge Nurse (LNA/CNA) 2.0 hprd LNA (CNA)	provided by LNA (CNA)
WA	To attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.	(RN, LPN/LVN) 1 DON RN full-time and 1 RN/LPN Charge Nurse each tour of duty including 1 RN 16 hrs/7d/wk and 1 RN/LPN "directly supervising resident care"for the other 8 hrs/7 days a week	No minimum requirement
WI	To meet the specific needs of each resident.	(RN, LPN/LVN) 1 DON RN full-time Day and For 1-59 residents: DON RN may be Charge Nurse or other RN 1 Charge Nurse on duty at all times 0.65 LN hprd for intensive skilled nursing 0.5 LN hprd for skilled nursing 0.4 LN hprd for intermediate nursing	For intensive skilled nursing care, 3.25 hprd including 0.65 LN hprd For skilled nursing care, 2.5 hprd including 0.5 LN hprd For intermediate or limited nursing care, 2.0 hprd including 0.4 LN hprd
WV	To attain or maintain the highest practicable physical, mental, and psychosocial well being of each resident	(RN, LPN/LVN) 1 DON RN full-time Day 8hrs/5days/wk and 1 RN/LPN Charge Nurse each unit each shift 1 RN on duty 8 consecutive hrs/7days/wk: For less than 60 beds, DON can count as RN If no RN on duty, a RN must be on call	2.25 hprd (RN/LVN/CNA) 51 or fewer beds have higher staffing required For 60+ beds: exclude DON
WY	To meet the total needs of the residents	(RN, LPN/LVN) 1 DON full-time RN and 1 RN/LPN Charge Nurse on Days 7days/week for each nursing station and 1 RN/LPN all other tours of duty (DON excluded for 60+ beds)	2.25 hprd per 24 hrs/7days/week

APPENDIX D – IRB Letter

FWA #00000287

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NOT HUMAN SUBJECTS RESEARCH
DETERMINATION NOTICE
STUDENT PROJECTS

Date: November 18, 2015

To: Susan C. Lynch

Re: **DrPH Dissertation Student Project Title:** "Examination of the Effect of Corporate Integrity Agreements on Skilled Nursing Facility Quality of Care, as Measured by Percent of Long-Stay Residents with Pressure Ulcers and using Indwelling Catheters"

The JHSPH IRB reviewed the IRB Office Determination Request Form for Secondary Data Analysis (received November 15, 2015) on **November 18, 2015**. We have determined that the proposed activity described in your request form will involve secondary data analysis of existing, de-identified and de-linked publicly available datasets. Thus, the proposed activity does not qualify as human subjects research as defined by DHHS regulations 45 CFR 46.102, and does not require IRB oversight.

You are responsible for notifying the JHSPH IRB of any future changes that might involve human subjects and require IRB review.

If you have any questions regarding this determination, please contact the JHSPH IRB Office at (410) 955-3193 or via email at jhsph.irboffice@jhu.edu.

/teb

cc: Laura Morlock, PhD
Faculty Advisor / Professor
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HEALTH LAW EXPERIENCE

UNITED STATES DEPARTMENT OF JUSTICE, Washington, DC
CIVIL DIVISION, FRAUD SECTION
Lead Counsel, Elder Justice Initiative, 2010-present
Trial Attorney, Civil Fraud Section, 1999–present

Health Care Fraud Litigation Practice

- Lead national multi-district civil health care fraud investigations and manage False Claims Act cases
- Cases focus on health care fraud involving all of the following providers: skilled nursing facilities, home health agencies, hospices, hospital systems, specialty physician practices, long-term acute care hospitals, pharmaceutical companies, medical device manufacturers, rural health providers, and air ambulance companies
- Responsible for all aspects of investigations and litigation, including establishing investigative plans, coordinating parallel investigations with criminal prosecutors, supervising FBI agents and investigators, negotiating settlements, taking and defending depositions, and arguing substantive motions in numerous federal district courts
- Lead counsel in mediations, evidentiary hearings, and trials

Significant Health Care Fraud Recoveries

- **Lead counsel on national case involving home health care fraud ($66 million federal civil fraud settlement)**
- **Lead counsel on the Department's largest failure of care skilled nursing facility settlement ($38 million)**
- Lead counsel on national multi-district investigation involving 25 *qui tam* cases in 12 states against a skilled nursing home chain ($34 million federal civil fraud settlement)
- Lead counsel on Anti-kickback case involving therapy providers ($30 million federal civil fraud settlement)
- Lead counsel on home health cost report fraud case ($9.5 million federal civil fraud settlement)
- Lead counsel on one of the Department's first recoveries on a False Claims Act failure of care legal theory against a large nursing home chain ($1.25 million federal/state civil fraud settlement)
- Co-counsel on a managed care plan cherry-picking fraud case ($144 million federal/state civil fraud judgment)

Elder Justice and Quality of Care Policy Work

- Selected to represent DOJ on the 2015 White House Conference on Aging Elder Justice Working Group
- Directed the development of the DOJ Elder Justice Website
- Selected to be a DOJ representative on the federal interagency Elder Justice Working Group
- Selected to be national lead counsel for DOJ's Nursing Home and Elder Justice Initiative's failure of care cases
- Work with the HHS Office of Inspector General on Corporate Integrity Agreements and Quality Monitors for skilled nursing facility chains, acute care hospitals, oncology practices, therapy providers, and individual physicians

Awards and Honors

- Presented with the Civil Division Award for directing the development of the DOJ Elder Justice Website (2014)
- Achieved one of the top ten settlements in the Fraud Section (2002, 2008, and 2011)
- Received the Attorney General's Special Commendation Award for $105 million civil fraud settlement (2007)
- Received Special Achievement Award from the United States Attorney for the District of Montana for obtaining the largest civil fraud damage award in Montana's history (2002)
- National Initiative Leader for Attorney General Janet Reno's Nursing National Home Initiative (2000-2001)

Significant Professional Speaking Engagements

- 2015 White House Conference on Aging Dementia and Elder Justice presentation, April 2015
- Health Care Compliance Association Seminar: Quality in Long-term Care, May 2013
- Institute of Medicine: Elder Abuse Summit, April 2013
- ABA Webinar: Quality of Care: The New Frontier of Health Care Fraud Enforcement, May 2012
- United States Department of Justice Southern Regional Nursing Home Conferences, 1999 to 2002

HEALTH AND AGING POLICY FELLOW (THROUGH JHSPH), Washington, DC
CMS Placement, Survey and Certification Group, Division of Nursing Homes, 2012-2014

- Worked on National Initiative to Improve Dementia Care and Reduce Antipsychotic Use in Nursing Homes
- Worked on National Nursing Home Quality Care Collaborative

BALDRIGE PERFORMANCE EXCELLENCE PROGRAM, Gaithersburg, MD
National Baldrige Examiner, 2014 – present

- Selected in a highly competitive process to be a National Baldrige Examiner
- Reviewed and assessed healthcare entities and non-profit business and invited to a site visit

BRAND LOWELL & RYAN, PC, Washington, DC
Health Care and Litigation Associate, 1997–1999

- Tried federal fraud and state business conspiracy cases; presented witness testimony at trial
- Drafted briefs and discovery in civil and criminal matters
- Took and defended depositions; prepared witnesses for federal grand jury testimony

POWELL GOLDSTEIN, LLP Washington, DC
Health Care and Litigation Associate, 1996-1997

- Prepared research memoranda and briefs in complex civil litigation cases
- Assisted in the defense of a nursing home fraud and abuse case

BAYH CONNAUGHTON & MALONE, PC, Washington, DC
Health Care and Litigation Associate, 1993–1996
Summer Associate, 1992

- Analyzed all federal Health Care Plans proposed in 1993-1995
- Took and defended depositions; prepared witnesses for trial testimony; prepared briefs in complex civil cases
- Developed and directed the Firm's Pro Bono Program for 3 years
- Billed 2200 hours each year
- Published case: Stewart v. Lady, 251 Va. 106, 465 S.E.2d 782 (1996)(decision on non-stock corporate formalities)

US DISTRICT COURT FOR THE SOUTHERN DISTRICT OF INDIANA, Indianapolis, IN
Law Clerk Assistant to the Hon. Larry McKinney, 1992–1993

- Drafted opinions in civil and criminal cases

TEACHING EXPERIENCE

GEORGE WASHINGTON UNIVERSITY LAW SCHOOL, Washington, DC
Adjunct Professor of Law, 2000-present

- Teach upper-level course: Heath Care Fraud and Abuse Seminar (2013-present)
- Teach third-year seminar: Legal Drafting in Federal Civil Litigation (2006-present)
- Teach first-year law courses: Legal Research and Writing, and Appellate Advocacy (2000–present)

JOHNS HOPKINS UNIVERSITY BLOOMBERG SCHOOL OF PUBLIC HEALTH, Baltimore, MD
Guest Lecturer, 2003-2007

- Assisted in teaching modules in the Masters of Public Health capstone course "Problem Solving in Public Health"
- Guest Lecturer in the "Role of Government in Public Health" course

DEPARTMENT OF JUSTICE'S NATIONAL ADVOCACY CENTER, Columbia, SC
Instructor, 2000-present

- Taught seminars on nursing home fraud and abuse at the national and state levels

EDUCATION

JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH, Baltimore, MD
Doctor of Public Health in Health Policy and Management, DrPH Student (expected graduation date: May 2016)

- Current GPA 4.00
- Concentration in Gerontology, coursework includes: Health Issues for Aging Populations, Epidemiology of Aging, New Frontiers in Gerontology, Managing Long-Term Care Services for Aging Populations, and Palliative Care
- Awarded Certificate in Gerontology
- Awarded Certificate in Health Finance and Management
- Awarded The Pearl and Jeremiah German Scholarship in Gerontology
- Thesis: *Examination of the Effect of Corporate Integrity Agreements on Skilled Nursing Facility Quality of Care, as Measured by Rates of Pressure Ulcers and Indwelling Catheter Use* (2016)

Masters of Public Health (concentration in Health Policy), 2003

- GPA 3.85/4.00
- Selected for induction into the *Delta Omega* Public Health Honor Society
- Thesis: *Causation at the Intersection of Epidemiology and the Law: The Tobacco Litigation Case Study* (2003)

GEORGETOWN UNIVERSITY LAW CENTER, Washington, DC
LL.M. in Litigation and the Judicial Process, 2000

- GPA 3.83/4.00
- Graduated with Distinction
- *American Criminal Law Review* Editorial Board, 1997-1998
- Selected to be the LL.M. Class 2000 Commencement Speaker
- Thesis: *The Federal Grand Jury: Revisiting Reform* (2000)

INDIANA UNIVERSITY-BLOOMINGTON SCHOOL OF LAW, Bloomington, IN
Juris Doctor, 1993

- *Indiana Law Journal of Global Legal Studies* - Editor-in-Chief, 1992-1993
- Elected to the National Order of the Barristers - designated one of the top ten advocates in the graduating class
- National Negotiations Team - won 1992 Midwest Regionals; placed 8th in 1993 Nationals

DARTMOUTH COLLEGE, Hanover, NH
Bachelor of Arts in American History, 1988

- Dean's List - 5 terms
- Valedictorian Award – (awarded to incoming freshman who were the valedictorian of the high school class)

ADMISSIONS TO PRACTICE

- Licensed to practice in Maryland, 1993; currently waiving into the District of Columbia
- Admitted to Supreme Court of the United States; U.S. Courts of Appeals for the Third, Seventh and Ninth Circuits

LEGAL PUBLICATIONS

- Reporter and Author, Council for Court Excellence *DC Grand Jury Study Report* (2001)
- Article, *Recent Developments in the RICO Statute*, 35 AM. CRIM. L. REV. 1157, Number 3 (1998)
- Article, *Exporters, Project Developers Note: Eximbank Opportunities Abound*, THE ADVOCATE (1994)

PROFESSIONAL ASSOCIATIONS

- Council for Court Excellence - Board of Directors Member, 1998 – present
- Appointed to the Indiana University School of Law – Bloomington Alumni Executive Board, October 2007
- Edward Bennett Williams Inn of Court – Barrister Member – 2005 to present
- Women's Bar Association of the District of Columbia – Health Care Section, Co-Chair, 1995 –1997

- American Health Lawyers Association – Member
- American Public Health Association – Member
- Marathoner – Boston Marathon: 10 races; numerous ultramarathons.